Review Article

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Advancements in Management of Diabeties Mellitus

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ABSTRACT

Introduction: Diabetes is a group of metabolic disease in which there are high blood sugars for a prolonged period, if untreated leads to many life-threatening complications. Diabetes is due to either the pancreas not producing enough insulin or the cells of the body not responding properly to insulin.

Definition: Diabetes is a chronic metabolic disease characterized by elevated levels of blood glucose which leads over time to serious damage to heart, blood vessels, eyes, kidney and nerves.

Incidence:

- IDF Global Diabetes Atlas provides estimated and projected prevalence rate of diabetes around the world. Its most recent data from 2021 shows that China has the largest number of adults with diabetes aged 20-79 years followed by India and Pakistan.
- 463 million people globally are diagnosed with diabetes. In that 88 million are from south east Asia, out of that 88 million, 77 million are from India.
- The most affected rate in India is the economically and epidemiologically advanced states that is Kerala and Tamil Nadu. Kerala is the diabetic capital of India.
- In Telangana 26% above 30 years are diagnosed and are at high risk. Total 8% of the people of whole Telangana are diabetics.
- The incidence of diabetes has been increasing significantly on a global level. According to the latest statistics issued by the International Diabetes Federation, the number of adult diabetes cases reached 463 million worldwide in 2019, and it is anticipated to rise to 700 million cases by 2045. With the growing prevalence of diabetes, the economic cost has become burden some. The total cost of US-diagnosed diabetes in 2017 was estimated by the American Diabetes Association to be $327 billion, with an average individual expense of $16,752 er year. These figures demonstrate the significance of diabetes and encourage scientists and researchers to develop innovative solutions to make the lives of diabetics easier.

Keywords: Diabetes; Metabolic disease; High blood sugars; Life-threatening; Pancreas; Insulin.

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INTRODUCTION

Glucose monitoring is an important part of diabetes management, from self-monitoring of fasting and postprandial 2-h blood glucose to continuous glucose monitoring (CGM). Other metrics for monitoring diabetes include glycated haemoglobin A1c (HbA,) and glycated albumin (GA). Among these, self-monitoring of blood glucose (SMBG) is the basic form of glucose monitoring, where as HbA1c is a gold standard for assessing glycaemic control. However, HbA1c and SMBG have their own limitations. The HbA1c reflects the mean blood glucose (MBG) level over the past 2-3 months. Thus, there is a "delayed effect" for assessing the efficacy of a treatment. More over, HbA1c cannot accurately predict the risk of hypoglycaemia, nor does it fully reflect the characteristics of blood glucose fluctuations.

Continuous Glucose Monitoring (CGM)

CGM continuously monitors the glucose in concentrations in subcutaneous interstitial fluid through a glucose sensor. It can detect occult hyperglycaemia, hypoglycaemia, and the trends in glycaemic changes that cannot be routinely detected the by self-monitoring of blood glucose (SMBG), there by more comprehensively reflecting the characteristics of glycaemic fluctuations.

Continuous glucose monitoring (CGM) sensors are portable devices that allow measuring and visualizing the glucose concentration almost continuously (usually every 1–5 min) for several days (so far up to seven days).

Components of Continuous Glucose Monitor

CGM sensors are composed of three main elements:

i. *A needle based sensor:* Which is usually inserted in the abdominal subcutis and measures an electrical signal proportional to the glucose concentration present in the interstitial fluid.

ii. *Transmitter*: Which is applied over the sensor and is aimed at transmitting the signal.

iii. *Monitor:* A portable device, which receives the signal and visualizes it on a monitor.

Special Features of a CGM

CGM uses subcutaneous sensors to measure glucose levels in interstitial fluid.

CGM can be done two ways: intermittently scanned (CGM), where patients scan the sensor transmitter on demand using a receiver or their smartphone, or in real time (rtCGM), where the transmitter automatically sends glucose values to the patient's receiver or smartphone every one to five minutes, along with alerts when blood glucose levels fall outside accepted parameters.

CGMs are always on and recording glucose level even during showering, working, exercising, or sleeping. Many CGMs have special features that work with information from glucose readings:

- An alarm can sound when glucose level goes too low or too high.
- Can note meals, physical activity, and medicines in a CGM device, too, alongside your glucose levels.
- It is easy to download data to a computer or smart device to more easily see glucose trends.

Some models can send information right away to a second person's smartphone perhaps a parent, partner, or caregiver. For example, if a child's glucose drops dangerously low over night, the CGM could be set to wake a parent in the next room.

Currently, one CGM model is approved for treatment decisions, the Dexcom G5 Mobile. That means person can make changes to diabetes care plan based on CGM results alone.

Indications of CGM

- Person who is on intensive insulin therapy.
- Hhypoglycaemia unawareness.
- Frequently having high or low blood glucose.

Advantages of Continuous Glucose Monitoring

- Glucose levels can be tracked throughout the day and night.
- Glucose levels can be checked during the night when the levels are generally not tested.
- A rise or drop in glucose levels can be tracked, which will help people with diabetes to take early action.
- CGM helps to reduce the number of finger prick tests.
- CGM can help improve the levels of HbA1c as it helps to tailor the insulin dose more carefully.
- It helps patients to reduce hypoglycaemia (low glucose) events, as they can notice a downward trend even before the sugar levels sharply drop.
- The device can be used to set triggers and alarms for very high and low glucose spikes.

- CGM helps evaluate and measure the effects of diet and exercise on sugar levels.
- It aids in determining the effectiveness of the treatment plan at a detailed level.

Things to Remember While Using a Continuous Glucose Monitor:

- The sensor needs to be replaced every 3 to 7 days, depending on the model used. When ever the sensor is changed, the transmitter has to be attached to the new sensor.
- Some devices need to be calibrated by checking the blood glucose on a glucose meter twice a day.

Limits of CGM:

- Although a CGM may provide a bigger picture of blood sugar trends over a 24-hour period, it is not a solution for everyone. Sometimes, depending on individual health insurance, CGMs may not be covered and generally have higher out of pocket cost than standard blood glucose monitoring devices.
- Another limitation is that the glucose values from CGMs are interstitial fluid glucose measurements and may not be reliable because of the body fluid shifts,".
- With CGM, the ISF glucose levels may not always match the actual blood sugar levels. This is why it's important to use CGM as a supplement to, and not a replacement for, finger-stick blood sugar testing. "There can be lags in glucose values between interstitial results of (CGM) and capillary results (finger sticks.
- Other drawbacks of CGM include:
- CGM doesn't eliminate the need for traditional finger stick blood glucose tests. Blood sugar may need to be checked twice per day using finger stick methods to ensure accuracy.
- Depending on the model, most CGM sensors need to be replaced every 3 to 7 days, which can be expensive.
- The use of acetaminophen, found in Tylenol, may cause false high readings.
- False low readings may occur when sleeping on the sensor.
- CGM devices require a technical understanding and the ability to interpret CGM readings and a data which may difficult for nantech savvy users.
- Routine maintenance may be needed depending on the model.

Insulin Pumps:

- Insulin pumps are small, computerized devices. They are about the size of a small cell phone. Insulin pumps deliver doses of insulin on a pre-programmed schedule. Insulin is the hormone that regulates your blood sugar.

Sites:

- Attached to a strap under your clothes.
- In your pocket.
- On your belt.
- With an adhesive patch on your stomach or arm.

Action:

- People who have diabetes don't make enough insulin naturally. Instead, they have to use insulin injections to manage their blood sugar.
- Pumps offer a steady stream of insulin so that you can have fewer needle sticks. They're also a good option for children or anyone who has trouble remembering their insulin injections. Because insulin pumps stay attached to the body, some people find an insulin pump more convenient than insulin pen injections.

Indications:

Using an insulin pump is a personal preference. You may want to use an insulin pump if you:

- Experience delays in food absorption.
- Are active and may want to pause insulin doses when exercising.
- Have severe reactions to low blood sugar.
- Have diabetes and are planning a pregnancy.

Insulin pumps can also be a good option for young people with Type 1 diabetes. A pump can deliver a steady supply of insulin, even for children and others who might have trouble sticking to a schedule for insulin injections.

Difference Between Traditional and Patch Insulin Pump:

- Traditional insulin pumps push insulin from a chamber within the pump through tubing to a site on the skin that is connected to a smaller flexible plastic tube (cannula). The cannula is a few millimetres long and

delivers the insulin underneath your skin.

- Insulin patch pumps also use a flexible plastic tube (cannula) under the skin, but the insulin delivery chamber and the cannula are part of one "pod" that sits in the skin with an adhesive patch. You can place the patch directly on your belly or arm. There is no external tubing with a patch pump, and it's controlled wirelessly with a handheld controller.
- The tubing and cannula are removed and replaced every two to three days. A healthcare provider called a Diabetes Care and Education Specialist will show you how to do this.
- Common insulin pump brands include:
- Medtronic (MiniMed™)
- Omnipod®
- Tandem

An insulin pump delivers insulin in one of two ways:

- Small, continuous insulin doses (basal insulin).
- Surges of insulin near mealtimes (bolus insulin).
- While using an insulin pump, you still need to check your blood sugar levels. Most people check blood sugar at least four times a day. Or you may use a continuous glucose monitor.
- The pump uses information you enter about your food intake and blood sugar levels to calculate how much bolus insulin you need. The pump then recommends a bolus dose to you and waits for your approval before delivering. In addition, some pumps automatically adjust basal doses based on glucose levels from a continuous glucose monitor.

Risks / Benefits:

- Consistent, adjustable insulin delivery.
- Fewer insulin injections.
- Flexibility and privacy.
- Improved blood sugar levels.

Complications of Insulin Pumps:

Insulin pumps have a low risk of complication. Pumps provide more precise insulin doses than injections, so pumps may carry less risk for people who struggle with calculating their dosages.

Possible cons of using an insulin pump can include:

- Inability to hide the tubing or pump with non-patch styles.
- Higher cost than injections.
- Pumps breaking or tubing becoming disconnected.

There is also a risk of setting up the pump incorrectly. It's crucial to use the insulin pump properly and continue to check your blood sugar regularly. If you don't, you might not get the insulin you need, which can be dangerous and even life-threatening. First time users should ask their health care provider for setup instruction.

Insulin Pens

If syringes and insulin pumps don't work, consider insulin pens for convenient and quick doses of insulin.

Advantages:

- Insulin pens can make taking insulin more convenient because they combine the medication and syringe in one handy unit. Unlike syringes, pens come preloaded with insulin including premixed insulins.
- They are fairly simple to use: simply twist or snap on a new needle, dial a dose, inject the insulin, and throw away the used needle into a needle safe, sharps container. Certain insulin pens are disposable, so you can trash the pen once the insulin is gone or expired, while other pens can be reused once a new cartridge of insulin is inserted.
- Many brands offer pens that are color-coded and use different designs to help you know which type of insulin you're using at a glance. This makes the administration time faster than syringes and vials and they're more portable, too. Plus, some new models come with a digital application, to help you remember when you last injected insulin and how much was administered.
- hey're also less obvious than a vial and syringe, so you can administer insulin discreetly in public.

Disadvantages:

Pens vs. Syringes: The convenience factor of insulin pens means they cost more than syringes. Talk to your insurance provider to see if and how much they'll cover for insulin pens. Compare the costs of other diabetes management tools to see

which one makes the most sense.

Pens vs. Pumps: Despite the benefits, a draw back to using insulin pens (and syringes) is the need to administer insulin more often than if you were to use a pump. If you are particularly active and eat several times a day, you should consider the number of times a day you'll have to administer insulin versus that of a pump, which doesn't require shots.

Picking the right pen:

Pens come in two basic types: disposable and reusable.

- *Disposable pens* are preloaded with insulin and are thrown away after the insulin cartridge is empty or the pen has been in use for 28 or 32 days (depending on insulin type).
- *Reusable pens* work with insulin cartridges that can be loaded into the pen and then tossed away once the insulin is used, leaving the pen ready for the next cartridge. Each pen only works with certain types of insulin, so keep that in mind as you browse pens.
- Even though reusable pens are more expensive at first, replacement cartridges for reusable pens are cheaper than those for disposable, making them about the same price over the long term.

Don't forget the needles

- It's good practice to change needle after each injection or at least once daily. Fresh, sharp needles mean shots that are less painful.
- Most brands of pen needles will fit any of the insulin pens. Pen needles come in different lengths—between 4 and 12 mm—and gauges (thickness of the needle).

Length:

A shorter needle is effective for all body types. You want to aim to deliver the insulin just below the skin without hitting the muscle beneath. When using a shorter needle, administer at a 90-degree angle and do not pinch up the skin. Very thin people and children may want to pinch up the skin and inject at an angle even with a shorter needle to avoid hitting muscle. Hold the needle in the skin for 5 to 10 seconds after you give the insulin so the medication doesn't leak from the site.

Gauge

A higher gauge means a thinner needle and less pain, while a thicker needle may be more painful—length shouldn't really affect pain levels. If you inject a large dose of insulin at one time, a lower gauge (thicker) needle may make for quicker insulin delivery and help you to avoid medication leaking out of your skin.

Storing pens:

For unused pens, be sure to keep them refrigerated. For pens currently using, keep those at room temperature. Extreme temperatures should be avoided altogether, so they should stay out of the freezer. Also avoid leaving them in places where the temperature can get too hot or cold, such as on a windowsill or in a car, too. *Panelist - IV: Ms. Aleena Mathew.*

Smart Insulin:

- Smart insulin is a drug designed to circulate in the body and turn on when its needed and off when it's not needed.
- It is also called glucose responsive insulin. It is a promising treatment option for people with diabetes, helps to maintain blood glucose levels and remain within range during day.

Action:

Smart insulin automatically responds to change in blood sugar levels. The way in which it works is by using a molecule called a *binding element* when blood sugar is low, the binding element attaches to the insulin and prevents it from working, however as blood glucose level rise, glucose molecule frees the insulin from binding element this in turn allows the insulin to lower blood sugar levels back into balance.

BENEFITS:

- Automatically activates or deactivates in response to blood glucose.
- It would be transformative, it ll prevent high and low blood sugars which significantly reduces the need of regular blood glucose testing.
- Decrease the chances of long- and short-term complications.
- It eliminates not just hypo and hyper glycemia but also multiple daily injections.
- It could even make devices like artificial pancreas.
- Gives the patients confidence that they have enough insulin to cover their needs.

Pannelist-V: Ms. Mehfeen

Intestinal Bacteria as a Treatment for Diabetes Mellitus.

- Diabetes mellitus is an emerging health condition globally and is suggested to have a direct connection with the gut microbiota that determines our metabolic outcomes.
- Human body is inhabited by numerous microbesthatre sides on and with in the human body. These micro organisms constitute our micro biota and their complete genome is referred to as microbiome.
- Micro organisms existing from 10 to100 trillion in numbers survive in the adult gut with approximately 1000 species. Most of the bulk of the see microorganisms live in the bowel. The major constituents of gut flora a remainly bacteria a long with few viruses and fungi.
- The impact of gut micro biota in diabetes has been the talk of there searchers for the past few years. The researchers combined experiments on mice with the analysis of large quantities of data from previous research in mice. The scientists gave mice either regular diet or food equivalent to a western diet.
- As there searchers expected, mice fed a western diet developed glucose intolerance and insulin resistance which are the contributing factors to type 2 Diabetes.

They managed to narrow down the list of four bacteria that appeared to playa key role in reducing or intensifying the harmful effects of the western diet:

1. Lactobacillus johnsonii
2. Lactobacillus gasseri
3. Romboutsia ilealis and
4. Ruminococcus gnavu

- They also found that romboutsia ilealis was present in more than 80% of people with obesity which suggests that this micro be might contributeto obesity.
- The authors of the study now wanted to know what happens to the mice's metabolism when they receive the healthy diet and unhealthy diet to see if the bacteria could improve the metabolism of people with type 2 diabetes.
- Different strains of lactobacillus occurinmany fermented foods including certaindairy products such as yogurt.
- Miceona diet that contained R. ilealis showed a reduced glucose tolerance level and insulin production which suggests a diabetes like condition.

Fecal Microbiota Transplant:

- Early in life, the gut micro biota shapes the immune system and regulates metabolism, whereas imbalances in the gut micro biota later in life can cause severe autoimmune disorders.
- Long term restoration of gut micro biota through FMT may be used as a promising therapeutic application for diabetes. it was found to be safe and effective in several human clinical studies.
- FMT has significantly altered the composition of gut bacteria and to affect glycaemic control and insulin resistance in subjects with metabolic syndrome. Therefore, the recent research is more focussed on FMT for type I DM management.
- To serve as donor mice, KM mice were obtained and housed under constant temperature and humidity conditions for 1 week.
- Insulin levels were tested by ELISA and related indexes. We found that insulin resistance and pancreatic islet β-cells were improved after FMT treatment. Meanwhile, the markers of inflammation in the pancreatic tissue were detected by ELISA and immune his to chemistry, which indicated that inflammatory response decreased following FMT treatment.

Panelist-Vii:ms.irin

Diabetic Patches

Introduction

- Glycogen is an extensively branched glucose polymer that animal use as an energy reserve. Glycogen has implication in glucose hemostasis. Glycogen is highly concentrated in the liver all though muscle contain the most glycogen by weight.
- Hypoglycemia is one of the most indications for ZP-glycogen patch. It is a common problem in people living with diabetes who are in insulin and insulin secretagogue (drug that increase insulin secretion by pancreas).
- Micro needle technology as a method of transdermal drug delivery has received a deal of attention in recent years. Micro needles consist of micro-scale projections that are considered to be minimally invasive, yet are capable of bypassing the outer layer of the

skin (stratum corneum) without disrupting nerves and blood vessels thereby inducing no pain or bleeding when applied.

- The micro channel that results from the projection form an unobstructed transport pathway big enough for the large molecule such as protein and peptides to pass through.

Technology

- It is a coin sized (about 5 cms) adhesive polymer patch with micro needles. The pyramid shaped micro needles are 400 microns, wide at the base and 900 microns tall and penetrate stratum corneum, the outer layer of the skin.
- When the interstitial fluids in the skin reach hyperglycemic levels, the phenylboronic acid unit within the polymer matrix promote swelling of needles ae release the insulin preloaded into the matrix.
- Controlled studies on the diabetic's mini pigs showed the patches would maintain the pig's glucose level in a normal range more than 20 hours, according the quality of paper. When the patch is applied the micro needle physically break the outer layer of skin and penetrate the epidermis layer below where the drug coating is dissolved in the surrounding interstitial fluid. the outer layer of the skin provides protection against external microbial pathogens chemical and dehydration and us also the physical barrier to drug intended for transdermal delivery.

Sites of Placing Patches

- Peel off adhesive.
- Place the patches over the naval area.
- Back off the upper arm.
- This is recommended for 14-75 age group, and these patches have to be changed every 7 days.
- Chest and arm are most preferred.

Artificial Pancreas:

- The Artificial Pancreas Device System is a system of devices that closely mimics the glucose regulating function of the healthy pancreas.
- It senses the blood glucose level, determining the amount of insulin needed, and then delivering the appropriate amount of insulin.
- Sometimes an Artificial Pancreas Device System is referred to as' Closed Loop System', an' Automated Insulin Delivery System', or an 'Autonomous System for Glycemic Control'.
- The first hybrid Closed Loop System, the Medtronic's 670G System is the first FDA approved artificial pancreas. The FDA approved it for treating Type1 Diabetes in people age 14 and older. The Artificial Pancreases hit the market in 2016.

Function / Mechanism of Artificial Pancreas Device System:

- Monitors Glucose levels
- Hyperglycaemia
- Delivers insulin Monitors Glucose levels Hypoglycaemia
- Do not deliver insulin

Components of Artificial Pancreas:

There are 4 components of Artificial Pancreas;

1. **Continuous Glucose monitor (CGM):**

- ACGM provide steady stream of information that reflects that Patient's blood glucose levels.
- A Sensor placed under the patient's skin (Subcutaneously) measures the glucose in the fluid around the cells (Interstitial fluid) which is associated with blood glucose levels.
- A small transmitter sends in formation to a receiver.
- ACGM continuously displays both an estimate of blood glucose levels and their direction and rate of change of these estimates.

2. **Continuous Glucose monitor receiver:**

- CGM Monitor displays the update reading as a graph and tends minutes by minutes and translate the reading from USB to Bluetooth.
- The CGM receiver was inserted into the translator, which translated a serial USB protocol into a Bluetooth communication protocol.

3. **Control Algorithm device:**

- A control Algorithm is a software embedded in an external processor (Controller) that receives information from the CGM and performs a series of mathematical calculations.
- Base do n the se calculations, the controller sends dosing instruction to the in fusion

pumps.

- The control Algorithm can brunon any number of devices including an insulin pump, Computer, Smartphone or Tablet.

4. Insulin Pump:

- Based on the instructions sent by the controller, an infusion pump adjusts the insulin delivery to the tissue under the skin.

Types of Artificial Pancreas System:

There are several types of artificial pancreas systems. They include:

1. Threshold suspend and predictive suspend systems:

- *The threshold suspends and predictive suspend systems* can temporarily stop or "suspend" delivering insulin if blood glucose level gets low.
- *The threshold suspend system* stops delivering insulin when blood glucose level drop store set level.
- *The predictive suspend system* calculates blood glucose level and will stop delivering insulin before blood glucose level gets too low. Neither system automatically increases insulin doses.

2. Insulin only systems:

- Insulin only systems keep blood glucose level with in target range by automatically increasing or decreasing the amount of insulin delivered to body base do CGM values. Insulin-only systems can increase insulin doses if blood glucose level is higher than target range.
- One type of insulin-only system is the hybrid system. The hybrid insulin-only system automatically adjusts insulin doses in response to CGM values. But one must still count carbohydrate levels and calculate insulin doses for all meals and snacks.

3. Dual hormone systems:

- Researchers are currently developing and testing systems that use two hormones insulin to lower glucose levels and glucagon to raise blood glucose levels.
- Using two hormones to control blood glucose is similar to the way the pancreas works in people who do not have diabetes. These systems may be able to tightly control glucose levels without causing hypoglycemia.

Advantages

- Less of burden on Diabetics to maintain blood glucose levels.
- Blood glucose levels maintained lessen future costly complications for Diabetics.
- Potential life enhancer for patients with diabetes.
- The continuous blood glucose monitor predicts again slow and high blood glucose levels.
- One step closer to complete cure for Diabetics.

Disadvantages

- Nota complete cure for Diabetics.
- Artificial Pancreas is an external device that must be carried and connected at all times.
- Difficult for athletic Diabetics who play contact sports to maintain device connected.
- Still need to supplement the machines and maintain them.
- Artificial Pancreas potential has life threatening risks of patient with diabetes if it were to malfunction.

Immunotherapy as a Vaccine for Type 1

- Immunotherapy or biological therapy is treatment of disease by activating or suppressing immune system. Immune therapy is mostly known as modern treatment for allergies where a person is exposed to a small amount of what they are allergic train order to train immune system to tolerate it.
- The principle of modulating immune system to either attack or tolerate specific target has gained a lot of recognition in recent years.
- As autoimmune disease is directly caused by the immune system, immunotherapy have started being investigated as an approach to treat a number of different autoimmune condition, among type 1 diabetes.
- For decades, type 1 DM treatment has focused on treating the condition, mainly with insulin. In recent years, however the rapies that target immune system have gained more and more tract in their potential to delay or prevent type 1 dm.
- You may have heard about a new drug called talizumab, which has gained much excitement due to its potential to target immune system and delay a diagnosis of type 1 for two years or more.

- A vaccine known as Diamyd, while not as far along as a potential immunotherapy for type 1 dm.

Aim: The Diamyd vaccine aims to stop the destruction of insulin producing beta cells that lead to T1D.

All About Vaccine:

- The active ingredient in the vaccine is GAD65 (glutamic acid decarboxylase-65), an enzyme that occurs naturally in the pancreatic beta cells that helps them work properly and continue producing insulin. A majority of people with T1D have GAD auto anti bodies that target this enzyme, leading the immune system to attack the cells that make insulin, shutting off insulin production.
- Diamyd's vaccine supplements the GAD65 enzyme, aiming to stop this destructive process. It could thwart or delay the on set of T1D by helping the beta cells continue to produce insulin.
- In earlier clinical trials, the Diamyd vaccine was injected directly into the lymph nodes of children and young adults (ages 12 to 24) who had been diagnosed with T1D within the past 6 months. They received three or four injections over the course of 15 months. Results showed a "significant effect on C-peptide retention," meaning it preserved or improved insulin secretion in the body.
- In the upcoming Phase III trials, subjects will be randomized to receive either three injections of the Diamyd vaccine or three injections of a placebo one month apart. The outcomes will be measured after 24 months. Based on efficacy data from previous trials, the company is confident that C-peptide levels will be preserved, and participants will see lower A1C results (indicating improved blood sugar levels).
- Indication: Diamyd is indicated for individuals recently diagnosed with type 1 diabetes who carry the genetic HLA DR3-DQ2 haplo type.
- This is a randomized, placebo-controlled phase II study to investigate if a prime and boost of 20ug Diamyd® (rhGAD65 formulated in Alhydrogel®), administered subcutaneously four weeks apart, is safe and can preserve beta-cell function in children and adolescents with type 1 diabetes with diabetes diagnosis duration less than 18 months at intervention.

Objective

The objective of *Diagnode*-3 is to evaluate the efficacy and safety of three intranodal injections of 4 µg of Diamyd compared to placebo, along with oral Vitamin D supplementation, to preserve endogenous beta cell function and influence glycemic parameters in adolescent and adults recently diagnosed with T1D carrying the *HLA DR3-DQ2* haplotype.

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