

Glucose clamp study

linear

*Innovating with our client to support
a novel needle-free insulin delivery therapy.*



Nobody likes needles and injections. Unfortunately though, insulin injections are a fact of life for diabetics and their carers the world over.

So when a prospective client asked us to take on a trial for a new needle-free insulin delivery system, our team was immediately up for the challenge of the glucose-clamp study – the complexity of which had baffled and deterred the other clinical trials facilities our sponsor had approached. Just the sort of challenge we relish.

The challenge

Even as the only clinical trials site in Australia willing and able to perform this trial, the complex protocol for this eight-way crossover study meant our team had to invest in new specialised equipment, as well as extensive training for our laboratory and clinical teams.

The key to the study was monitoring the blood glucose levels of our participants every ten minutes to maintain glucose blood levels during the clamp, providing a precisely calibrated glucose/insulin intervention immediately in the event of a deviation.

Key requirements

- + Maintaining a *tight glucose blood level* during the clamp (18-24 hours)
- + *Monitoring* blood glucose level every ten minutes for 6-12 hours
- + *Intervening* rapidly if the blood glucose level went outside normal range
- + *Quantifying* the glucose to give in response to a deviation, fast
- + Facilitating *real-time communication* between unit, lab and medical teams

What is glucose clamping?

The glucose clamp technique is used to measure how well you metabolise glucose and how sensitive you are to insulin. It's a delicate but vital technique in the development of diabetes therapies, whereby your glucose is monitored and effectively 'clamped' at a certain concentration.

The solution

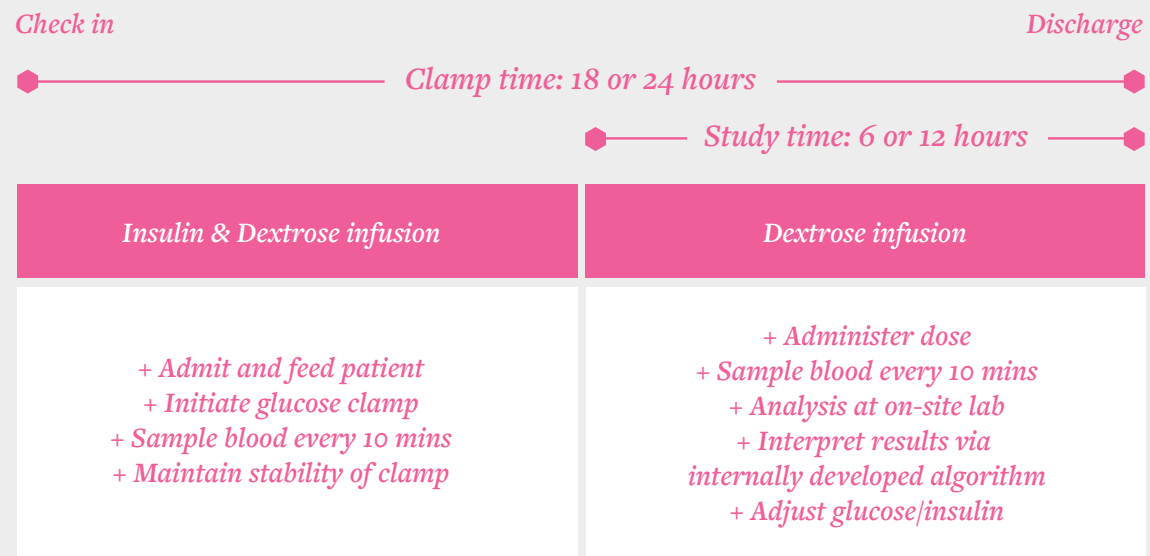
The study was as much an organisational and logistical challenge as a clinical and medical one. As such, it called for a huge round-the-clock collaborative effort, not only from our medical, nursing and laboratory teams, but with our external clinical research, glucose specialist and YSI training partners.

Because the glucose clamp technique demands such precision and speed, we had

to develop a number of innovative solutions in-house.

Most notably, this included creating an online collaboration space where results could be shared, interpreted and responded to in real time, along with a new algorithm and tool for calculating glucose doses instantly.

Trial workflow



Key deliverables and innovations

- + **Flexible 24/7 shifts** for clinical, medical and study teams, a 5:1 staff-patient ratio
- + **Specialised clinical area** with extra bedside space for intensive staff requirements
- + **Collaborative** online space for internal and external clinical, medical and lab teams
- + **New integrated online tool** to enable rapid decision making on glucose dosing
- + **Glucose clamp manual**, training materials and visual aids created by our medical team

The outcome

Our sponsor is very happy with the way the trial was conducted, both in practical terms – completed on time and on budget – but in the way our team adapted and openly collaborated to ensure the study added tangible value to the development of their needle-free diabetes therapy.

From the online tools we developed, through to the way our team adapted to facilitate such a complex study, the quality of our work and input will have a direct impact on the development of our sponsor's product and, ultimately, the quality of life of people living with diabetes.

Key achievements

- + **Over 100** glucose clamp trials safely conducted and successfully completed
- + Timely, **on-budget** completion with efficient data cleaning and high quality reporting
- + **100% uptime** for all essential equipment and 24/7 medical and study staffing
- + **Ongoing input and feedback** to our sponsor from start to finish
- + **New skills, training and innovations** developed specifically for glucose clamp trials
- + Recommendations that have **enhanced** the **development** of our sponsor's product

“The Phase I study we conducted with Linear was all of intricate, intensive and novel. Despite these challenges, Linear were impressive in their professionalism and commitment to delivering results and ensuring the study was a success. Their technical competence and medical judgment was sound, and their willing attitude very refreshing. The smooth running of the study with minimal problems was an unqualified reflection of the Linear's team responsiveness, attention to detail, and problem solving mindset.”

Craig Cook, CEO, Midatech

To learn how Linear can help your first-in-human studies, please get in touch.

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