Performance of Menarini CGM during normal daily life activities

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25228

Source
Nationaal Trial Register

Brief title
TBA

Health condition

Diabetes Mellitus

Sponsors and support

Primary sponsor: Isala, Zwolle Dr. Van Heesweg 2, 8025 AB Zwolle Postbus 10400, 8000 GK Zwolle
Source(s) of monetary or material Support: Menarini

Intervention

Outcome measures

Primary outcome

The performance of the M-CGM compared to Nova capillary test strip during the 14-day study period.

Secondary outcome

The performance of the M-CGM compared to concomitantly used own FGM or rt-CGM device

Study description

Background summary

In subjects with diabetes, adequate to good metabolic control is necessary for a variety of reasons. Diabetes therapy requires intensive self-management from patients with diabetes type 1 including at least four times measurement of glucose concentrations and injection of the blood glucose lowering hormone insulin. If used appropriately, with rt-CGM the user often only needs to calibrate the sensor at some time points daily and being able to act and react on alarms preset at certain cut-off points. The aim of this study is to determine the performance (compared to capillary measurements) of a CGM during daily life in subjects with diabetes

Study objective

N/A

Study design

Start study: 2-11-2020

Wearing the GlucoMen® Day CGM for 14 days: 10-11-2020 through 10-12-2020

End of study: 30-1-2020

Intervention

Wearing a CGM to assess reliability and accuracy of glucose measurements. Specifically: comparison of the device with capillary measurements.

Contacts

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Eligibility criteria

Inclusion criteria

Subjects with type 1 diabetes mellitus, using insulin either by MDI or CSII.
Ability to provide oral and written informed consent

Exclusion criteria

Main exclusion criteria are the inability to understand the Dutch language and the presence of a severe or unstable medical condition.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-11-2020
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9039
CCMO	NL.74404.075.20

Study results