The influence of the needle length on long term glycaemic control in insulin using obese diabetic subjects

Published: 22-06-2007
Last updated: 08-05-2024

The main objective is to investigate if the use of 5mm needles has a positive effect concerning hypoglycemic events and local complaints like bruising, bleeding, back flow of insulin and pain compared to 8mm needles, and to receive information about...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON31505

Source
ToetsingOnline

Brief title
INOBESE

Condition

- Diabetic complications

Synonym
diabetes (insulin administration)

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: unrestricted research grant from Becton Dickinson

Intervention

Keyword: Diabetes mellitus, injection devices, Insulin administration, Needle length

Outcome measures

Primary outcome

hypoglycemia, local complaints, and patients preference.

Secondary outcome

HbA1c , fructosamine, serum 1,5-Anhydroglucitol

Study description

Background summary

For the administration of insulin, different needles are available with a length from 5 to 12.7mm. Insulin injections with a needle of 8 mm is injected in a lifted skinfold, a 5 mm needle can by used without lifting a skinfold (1). In the Netherlands obese people (BMI >= 30) are usually advised to use an 8mm or even longer needle (1). Increased BMI and the thickness of the subcutaneous tissue slow insulin absorption (2, 3, 4), possibly related to reduced subcutaneous blood flow. Furthermore, the capillaries are located just under the skin and between the fat and muscle layer. This could possibly determine the absorbing speed (2). It is not know if the administration of insulin with a 5mm needle by obese people has a different influence on the HbA1c compared to longer needles. The hypothesis of this study is that for the purpose of insulin injections, a 5 mm needle can be used without negative effects on metabolic parameters in patients with Diabetes Mellitus (DM) and a Body Mass Index (BMI) >= 30.

Study objective

The main objective is to investigate if the use of 5mm needles has a positive effect concerning hypoglycemic events and local complaints like bruising, bleeding, back flow of insulin and pain compared to 8mm needles, and to receive information about the preference of the patients.
The secondary objective is to investigate if insulin administrated with a 5mm needle is not inferior with respect to metabolic control compared to insulin injections with an 8mm needle.

Study design

A clinical trial with a cross-over design, with 2 periods, comparing the use of the shorter and the standard needle in randomized order.

Intervention

The intervention in this study is a specific needle with a length of 5 mm and 8 mm to be used with an insulin pen.

Study burden and risks

Burden: patients of one group will be requested to return to the longer needle. In a previous study (5) some patients refused to return to the longer needle. The patient will be asked to answer a questionnaire. Blood samples will be taken at the regular check up-visits of the patient. Taking a blood sample for HbA1c control is general practise.

Benefit: all patients who are prepared to join the study will have a check up of their injection sites. Patients with lipodystrophy will not be included but will get advice in injection technique. Included patients have the opportunity to try and compare the different needles and can continue using this needle after the study unless the results of this study show otherwise. During the regular laboratory check a blood sample will be taken for 1,5 anhydroglucitol and fructosamine. After the study these extra parameters can give the physician who treats the patient and the patient extra information about the glucose regulation. This information can help in improving the regulation.

Risk: the risk of injecting insulin is hypoglycaemia. Patients already use and inject insulin. Though previous study has not shown a risk of hypoglycaemia when switching to a different needle length patients will be advised to be extra alert for hypoglycaemic events when switching to a different needle.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
9700 RB Groningen
Nederland
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
9700 RB Groningen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

male and female adult patients diagnosed with Type 1 or Type 2 diabetes and using insulin for at least one year and have insulin injections with an insulin pen, have a BMI >= 30, have a skinfold thickness of > 10 mm at the injection sites, stable glycaemic control, hba1c between 6-10%, are capable of reading the written information and are prepared to, and capable of signing an informed consent.

Exclusion criteria

patients who: change their own insulin dosage and are not prepared to keep an administration of these changes, are hypoglycaemia unaware, are pregnant or wish to become pregnant, have a BMI < 30, have a skinfold thickness of <= 10mm, have skin problems including lipodystrophy

Study design

Design

Study type:	Interventional
Intervention model:	Crossover

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2007
Enrollment:	130
Type:	Actual

Medical products/devices used

Generic name:	needles for insulin administration
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL12394.042.07