Lipohypertrophy and endermotherapy® Effect of endermotherapy® treatment in insulin induced lipohypertrophy in type 1 and 2 Diabetes Mellitus patients.

Published: 22-12-2015
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Primary objective;Change in section and extent of treated LH after treatment with endermotherapy® and without treatment. Change in resistance and pain during injection at the right and left LH and changes in appearance aspects of LH right and left....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON44781

Source
ToetsingOnline

Brief title
Insulin induced lipohypertrophy and endermotherapy®

Condition

- Other condition
- Epidermal and dermal conditions

Synonym
injection sites, Insulin injections induced Lipohypertrophy

Health condition

Insuline geinduceerde lipohypertrofie bij DM1 en DM2

Research involving
Human

Sponsors and support

Primary sponsor: MediDerma centrum voor huid-oedeemtherapie
Source(s) of monetary or material Support: Zelf financiering MediDerma en onderzoeksgrant EADV

Intervention

Keyword: Endermotherapy, Insulin induced, Lipohypertrophy, type 1 and type 2 Diabetes Mellitus

Outcome measures

Primary outcome

* To determine a change in diameter and surface of treated LH after treatment

with endermotherapy® .

Secondary outcome

* To determine a change in diameter of untreated LH after nine weeks not

injecting

* To determine a change in surface of untreated LH after nine weeks not

injecting

* To determine a change in appearance aspect of untreated LH by researcher

* To determine a change in appearance aspect of treated LH by researcher

* To determine a change in appearance aspect of untreated LH by patient

* To determine a change in appearance aspect of treated LH by patient

* To determine pain when injected into untreated LH before start study

* To determine pain when injected into treated LH before start study

* To determine pain when injected into untreated LH in 10th week of study

* To determine pain when injected into treated LH in 10th week of study

* To determine resistance when injected in treated LH before start study

* To determine resistance when injected in untreated LH before start study

* To determine resistance when injected in treated LH in 10th week of study

* To determine resistance when injected untreated LH in 10th week of study

* To determine if there is a difference between the treatment effect at various

locations LH

* To determine if there is a difference between the treatment effect in short

term and long existing DM

* To determine if there is a difference between the treatment effect in short

term and long existing LH

* To determine if there is a difference between the treatment effect on the

different types of sex

Study description

Background summary

During treatments with endermotherapy® , which is used for various skin therapeutic indications, by chance a decrease in the presence of LH in DM patients is noticed and an improvement in injection capabilities.

Hypothesis
Twenty patients with bilateral insulin induced LH, single sided LH on the body will be treated with endermotherapy®. During this study insulin is not injected into both LH. The consistency of the treated LH is significantly improved after 10 endermotherapy® treatments.

Study objective

Primary objective;
Change in section and extent of treated LH after treatment with endermotherapy® and without treatment. Change in resistance and pain during injection at the right and left LH and changes in appearance aspects of LH right and left.

Secondary objectives;
Change in pain and resistance during injection at the LH and changes in appearance aspects of LH.
Locations of LH, years of attendance DM1 and DM2 at start study, years of LH at start study, LH presence in various sex.

Study design

Randomised single blinded pilot study.

Intervention

During 10 weeks, 20 patients will be treated single-sided in LH, 2 times a week during 10 minutes with endermotherapy®.

Study burden and risks

The population of patients is of age, able to regulate their own blood sugar independent and do not inject in to examined LH during the study. When injected in to examined LH there is an increased risk of hypoglycaemia because insulin can be better absorbed and distributed.
At the risk of hypoglycaemia there should be an independently intake of carbohydrates. The DM patient can compare this accelerated absorption of insulin with performing a sport / physical activity. In everyday life this is a standard anticipation for the DM1 and DM2 patient.

The study may only take place in patients with DM1 and DM2 which are mentally competent, older than 18 and up to 70 years and in whom there is bilateral insulin-induced LH. The treatments and measurements which are performed are non-invasive and without risk. Because the patient is instructed, during the nine weeks of the study, not to inject the examined LH, there is a low risk of hypoglycaemia. The participating patients should independently regulate their blood sugars.
At the end of 10 treatments, we expect that the treated LH will have changed.

Patient-related measurements

Measurement No. Week
LHVP patient questionnaire 5 1, 3, 5, 9, 10
Photography 3 1, 5, 9
Surface area measurements, 4 1, 3, 5, 9
Ultrasonic section measurements 4 1, 3, 5, 9
Harpenden section measurements 4 1, 3, 5, 9
Weight measurements 4 1, 3, 5, 9

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Type 1 and type 2 Diabetes Mellitus patients F/M, bilateral insulin injections induced lipohypertrophy (LH), from 18 to 70 years, able to use different injection sites instead of the lipohypertrophic sites (in consultation with diabetes care nurse), insulin injections in lipohypertophy is not allowed during research, ability,
able to regulate blood sugar independently. Willingness to leave body weight unchanged during research.

Exclusion criteria

Absence of insulin -induced bilateral LH, incompetent, under 18, over 70 years, prednison use, pregnancy, breastfeeding, malignant tumors and abnormalities in abdominal organs.

Heart failure, past 6 months myocardial infarction or stroke , renal dysfunction with the MDRD is below 50. Use of anticoagulants. No alternate injection sites, not able to regulate blood sugars.

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-03-2016
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	22-12-2015
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO Date:	17-05-2017
Application type:	Amendment
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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	NL52638.094.15