

Studying the effect of the correct insulin injection technique training and single use of needles for insulin pens on the control of blood glucose and daily dose of injected insulin in diabetic patients receiving multiple insulin injections

Submission date 27/02/2017	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 20/03/2017	Overall study status Completed	☐ Protocol
Last Edited 15/02/2022	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Background and study aims

Diabetes is a life-long condition where a person is unable to control their blood sugar levels. There are two main types of diabetes. In type 1 diabetes the body is unable to produce a hormone called insulin, which is responsible for breaking down glucose and turning it into energy. In type 2 diabetes the body either does not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). Insulin therapy is an essential part of treatment for many patients with both forms of diabetes. Patients can experience a range of issues when injecting insulin, resulting from improper technique and, ultimately, resulting in poor blood sugar control. The aim of this study is to find out whether patients who receive appropriate injection technique training and a supply of the required number of short insulin pen needles would achieve significantly greater blood sugar control and improved tolerability to injecting insulin compared with those who do not receive training or a supply of short insulin pen needles.

Who can participate?

Diabetic patients who inject insulin multiple times each day.

What does the study involve?

Participants are randomly allocated to one of three groups. Those in the first group receive structured training on the correct way to inject insulin and are provided with 4-mm needles for insulin injection pens based on the "one needle per injection" principle. Those in the second group receive structured training on the correct way to inject insulin but supply their own needles for their insulin injection pens. Those in the third group do not receive any training and supply their own needles for their insulin injection pens. All participants attend clinic visits at the

start of the study and three and six months later to have blood samples taken to assess their blood sugar control.

What are the possible benefits and risks of participating?

Participants who receive the training may benefit from being able to better control their blood sugar as they feel more able to inject insulin. There is a small risk of pain or bruising from blood testing.

Where is the study run from?

Moscow Regional Research and Clinical Institute (Russia)

When is the study starting and how long is it expected to run for?

April 2013 to January 2014

Who is funding the study?

Moscow Regional Research and Clinical Institute (Russia)

Who is the main contact?

Professor Inna V. Misnikova

inna-misnikova@mail.ru

Contact information

Type(s)

Public

Contact name

Prof Inna V. Misnikova

Contact details

Moscow Regional Research and Clinical Institute

61/2 Shepkina Street

Moscow

Russian Federation

129110

+7 495 688 95 93

inna-misnikova@mail.ru

Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

A randomized controlled trial to assess the impact of proper insulin injection technique training on glycemic control

Study objectives

Patients who receive appropriate injection technique training and a supply of the required number of short insulin pen needles would achieve significantly greater glycemic control and improved tolerability compared with those who did not receive training or a supply of short insulin pen needles.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local ethics committee of Moscow Regional Research and Clinical Institute, 13/06/2013, ref: 3

Study design

Single-centre randomized parallel open controlled study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Type 1 and Type 2 diabetes

Interventions

Participants are randomised to one of three groups using a table with random numbers generated by Statistika software.

Group 1: Patients with type 1 or 2 DM receiving multiple injections, who had structured training on the correct injection technique and were provided with 4-mm needles for insulin injection pens based on the "one needle per injection" principle

Group 2: Patients with type 1 or 2 DM receiving multiple injections, who had structured training on the correct injection technique but who supplied their own needles for insulin injection pens

Group 3 (control): Patients with type 1 or 2 DM receiving multiple injections, who did not have structured training on the correct injection technique and who supplied their own needles for insulin injection pens

All participants attend a total of 3 clinical visits (baseline visit [Days 1–5], month 3, and month 6) and 4 telephone follow-ups (month 1, 2, 4, and 5) over the 6-month study period..

Intervention Type

Behavioural

Primary outcome(s)

1. Blood glucose control is measured using the A1C test at baseline and 6 months
2. Fasting plasma glucose (FPG) is measured using the HemoCue® Glucose 201+ point-of-care glucometer (HemoCue AB, Angelholm, Sweden) at baseline and 6 months

Key secondary outcome(s)

1. Proportion of patients with A1C >9% is determined by A1C test performed using DCA Vantage Analyzer (Siemens Healthcare Diagnostics Inc., Malvern, PA, USA) at 6 months
2. Changes in insulin total daily dose (TDD), the frequency of needle reuse, and length of needle used before and after training is assessed by the investigator at study visits 1 and 6
3. Injection-related adverse events (AEs) are assessed by the investigator at each clinic visit. Visual examination and palpation of insulin injection sites to reveal LH and/or bruising was performed at baseline and the final study visit; patients were also questioned on the frequency of injection-related pain and bruising during these visits

Completion date

01/01/2014

Eligibility

Key inclusion criteria

1. Diagnosis of T1DM or T2DM
2. Aged 18 to 70 years
3. On multiple dose injection therapy (3 injections of prandial and 1 to 2 injections of basal insulin daily, prescribed as a pen injection and initiated at least 1 month before study entry)
4. Deemed ready to strictly adhere to the study protocol and scheduled physician visits
5. Provided written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

120

Key exclusion criteria

1. Presence of skin and soft tissue infections at the area of insulin injection
2. History of psychiatric disorders, mental deficiency, or language barrier that could adversely affect interactions with the treating physician in terms of achieving study objectives

Date of first enrolment

01/07/2013

Date of final enrolment

01/12/2013

Locations

Countries of recruitment

Russian Federation

Study participating centre

Moscow Regional Research and Clinical Institute

61/2 Shepkina Street

Moscow

Russian Federation

129110

Sponsor information

Organisation

Moscow Regional Research and Clinical Institute

Organisation

Becton Dickenson Diabetes Care

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Moscow Regional Research and Clinical Institute

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/12/2017	15/02/2022	Yes	No