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# 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

**Registration date**
20/03/2017

**Overall study status**
Completed

**Last Edited**
15/02/2022

**Condition category**
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] 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
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# Contact information

### Type(s)
Public

### Contact name
Prof Inna V. Misnikova

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

## Secondary study design
Randomised controlled trial

## Study setting(s)
GP practice

## Study type(s)
Treatment

## Participant information sheet
No participant information sheet available

## 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 measure
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

### Secondary outcome measures
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

### Overall study start date
22/04/2013

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
120

### 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
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129110

## Sponsor information

### Organisation
Moscow Regional Research and Clinical Institute

### Sponsor details
61/2 Shepkina Street
Moscow
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### Sponsor type
Hospital/treatment centre

### Organisation
Becton Dickenson Diabetes Care

### Sponsor details
1 Becton Drive
Franklin Lakes
United States of America
07417

### Sponsor type
Industry

## Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name
Moscow Regional Research and Clinical Institute

## Results and Publications

### Publication and dissemination plan
A publication in a high-impact peer-reviewed journal is planned for 2017.

The data were previously presented in 2016: Misnikova IV, Gubkin VA, Dreval AV, Lakeeva, TS. The role of proper insulin injection technique training in achieving good glycemic control. Oral presentation at: American Diabetes Association 76th Scientific Sessions, June 10–14, 2016, New Orleans, LA, USA.

### Intention to publish date
31/12/2017

### 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 |