

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of 32-Gauge with 4-mm Pen Needle and 8-mm Pen Needle efficiency on Glycemic Control, leakage, and pain in Type 2 diabetes Patients Referred to Razi Therapeutic and Educational Hospital, Rasht-2017

Protocol summary

Study aim

Determination of impact of Gauge-32 needles application with 4 and 8 mm lengths and the position of injection in the pain level, leakage after injection and blood sugar control of the patients with diabetes type II.

Design

In this research, the researched units with 207 individuals, are divided to two groups based on Random allocation rule and in one group, Gauge-32 with 4 mm length is used for injection and in another group, Gauge-32 with 8 mm length is used. Then based on crossover method, the used needles are substituted in each group with one another.

Settings and conduct

The injection is done by the researcher and the time of injection is chosen based on routine hospital ward. The researchers after their introduction to the educational and therapeutic center and refer to department of endocrinology and rheumatology of this center and after achieving agreement from the studied units, they started the process of the research.

Participants/Inclusion and exclusion criteria

Inclusion criteria: the patients with diabetes type II, age between 18-75, the diagnosis of diabetes type II, insulin injection at least for 2 years, BMI more than 18.5, no mental retardation and mental disorders and application of insulin is through insulin pen and exclusion criteria: no interest for participation in the research, no diabetes and suffering from skin disorders around the injection position.

Intervention groups

The effect of Gauge-32 application and the needles with 4 and 8 mm lengths are investigated in the intervention and control groups for insulin injection and the position change in response to pain level, leakage after injection and the blood sugar of diabetes type II patients.

Main outcome variables

The variations of the main consequence include: the pain, leakage after injection and blood sugar of the patient.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180213038720N1**

Registration date: **2018-09-03, 1397/06/12**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-03, 1397/06/12**

Update count: **0**

Registration date

2018-09-03, 1397/06/12

Registrant information

Name

Mostafa Soodmand

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-02, 1397/01/13

Expected recruitment end date

2018-09-04, 1397/06/13

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of 32-Gauge with 4-mm Pen Needle and 8-mm Pen Needle efficiency on Glycemic Control, leakage, and pain in Type 2 diabetes Patients Referred to Razi Therapeutic and Educational Hospital, Rasht-2017

Public title
Comparison of 32-Gauge with 4-mm Pen Needle and 8-mm Pen Needle efficiency on Glycemic Control, leakage, and pain in Type 2 Diabetes Patients

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria:
 Patient must be between 18 to 75 years old patient must have type 2 diabetes patient must have used injecting insulin at least for 2 years patient BMI must be over 18/5 Patient should not be mentally retired or have any psychological disease patient must use insulin pen
Exclusion criteria:
 Patient does not want to participate in the study. Patient has skin problems in the injection site. patient does not have diabetes.

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **207**

Randomization (investigator's opinion)
Randomized

Randomization description
This is a cross-sectional randomized clinical trial study. The study population was type 2 diabetic patients referring to the Razi Educational Center Endocrine Center of Rasht. The method is easy to select and is randomly assigned to two groups according to the random allocation rule.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Research and technology of Guilan University of Medical Sciences, Old Building, School of Health, In Front of the 17th Shahrivar Hospital, Shahid Siadati St, Namjoo Ave, Rasht, Iran

City

Rasht

Province

Guilan

Postal code

41469-39841

Approval date

2018-02-03, 1396/11/14

Ethics committee reference number

IR.GUMS.REC.1396.457

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Comparison of 2 Pen Needles efficiency on patient Glycemic Control

Timepoint

Comparison of 2 Pen Needle gauges efficiency on patient Glycemic Control that patient blood sugar will be distinct in first ,third and 6th day

Method of measurement

patient blood sugar will be distinct by blood sampling and laboratory instruments.

2

Description

Comparison of 2 pen needle Gauges efficiency on needle leakage

Timepoint

Comparison of 2 Pen Needle gauges efficiency on needle leakage that will be evaluated in first ,third and 6th day

Method of measurement

leakage will be approved by the researcher

3

Description

Comparison of 2 Pen Needles efficiency on patient pain while injection

Timepoint

Comparison of 2 Pen Needle gauges efficiency on needle pain that will be evaluated in first ,third and 6th day

Method of measurement

pain will be evaluated by the Visual Analogue Scale

Secondary outcomes

1

Description

None

Timepoint

None

Method of measurement

None

Intervention groups

1

Description

Considering the crossover nature of this clinical trial in the first intervention group (A): At first, during 3 days of first hospitalization week, the insulin injection is done by the researcher with 90 degree angle and by means of Gauge 32 needle with 4 mm length and at second intervention group (B): During the last 3 days of the first week of hospitalization, insulin injection with 90 degree angle and by means of Gauge 32 needle with 8 mm length is done by the researcher. Then for post cycle therapy for both groups, there is no intervention for one day and instead the routine treatment is followed. Then the groups are substituted with each other and in the second intervention (B): In 3 last days of first week hospitalization, the insulin injection with 90 degree angle and by means of Gauge-32 with 4 mm length is done by the researcher and in the first intervention group (A): In 3 last days of the first week hospitalization, the insulin injection with 90 degree angle and by means of Gauge-32 needle and 8 mm length is done by the researcher.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Therapeutic and Educational Center

Full name of responsible person

Hossein Rafiei

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Razi Therapeutic and Educational Center, Sardar jangal Street, Rasht, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr. Shademan Nemat

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Grant name

Student Research Committee

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rasht University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Hossein Rafiei

Position

Bachelor of science student

Latest degree

A Level or less

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mostafa Soodmand

Position

MSc Student Medical-Surgical of Nursing

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

Contact

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Collected data will be given to the individuals or organizations -a raw information- that will be provided with the consent of the participants without any name, address or telephone number, and other items

When the data will become available and for how long

after we have finished the study if data crashed or disposed it will be reachable in a raw information

To whom data/document is available

just those have a Written request from authoritative research organizations

Under which criteria data/document could be used

if there was need to be called in analysis field you can call 09116470641

From where data/document is obtainable

mostafa sodmand phone number: 09116470641

What processes are involved for a request to access data/document

after confirmation the requeste, only raw and unidentifiable information from the mail will be delivered within one week.

Comments

if you have any question about this study call these numbers 09116470641 09155328439 09113312939