Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Efficacy assessment of the Superporous Hydrogel (SPH) polymer-based oral insulin delivery systems on plasma glucose in patients with type 1 diabetes

Protocol summary

Summary

The present study will evaluate the efficacy and short-time complications of three types of SPH polymer-based oral insulin capsules on blood glucose in patients with type 1 diabetes. This study is a double blind, multi-stage clinical trial. Fifteen adult patients with type 1 diabetes mellitus are selected from diabetes clinic of Dr. Shariati General Hospital to participate in this study. Exclusion criteria are any previous hypersensitivity to polymer, clinically diagnosed diabetic gastroparesia, forcing patients to use drugs intervention with insulin during study, history of systemic disorders. The trial composes of a screening visit (visit 1) and five trial visits (visit 2-6). Screening includes medical history, physical examination and clinical and laboratory tests within one month prior to enter to the study. Trial visits consist of three types of oral insulin (800 IU/ core inside, 800 IU/core outside and 1600 IU/core outside), a placebo and subcutaneous (SC) administration of 0.1 IU/kg regular insulin. SC regular insulin study is performed on the first trial visit and all patients receive the other four types of capsules (three of oral insulin and a placebo) in randomized order visits. On the first day (SC insulin study) patients receive a meal 30 minutes after insulin injection. On the other four visits (oral insulin or placebo) patients receive the similar meal 180 minutes after ingestion of capsule. There are seven days between two visits as a wash-out period. Patients have not received long acting insulin during last 24 hours. Venous blood samples for determination of plasma glucose and insulin concentrations will collect: At injection visit, 0(immediately before dosing), 5, 15, 30 (immediately before the meal), 60, 90, 120, 180, 240, and 360min; and at oral capsule visit, 0 (immediately before dosing), 30, 60, 120, 150, 180(immediately before the meal), 210, 240, 300, 360 min. The patients are registered under the close supervision with the glucometer BS, vital sign, symptoms of hypoglycemia, and other possible complications during blood sampling and 48 hours after sampling and the existence of any form of symptoms and complications are recorded as being severe symptoms will be excluded from the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138808111414N4**
Registration date: **2010-05-03, 1389/02/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-05-03, 1389/02/13

Registrant information

Name

Bagher Larijani

Name of organization / entity

Endocrinology & Metabolism Research Center, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Endocrinology and Metabolism Research Center, Tehran University of Medical Sciences

Expected recruitment start date

2008-12-01, 1387/09/11

Expected recruitment end date
2009-03-26, 1388/01/06
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy assessment of the Superporous Hydrogel (SPH) polymer-based oral insulin delivery systems on plasma glucose in patients with type 1 diabetes

Public title
Efficacy assessment of the Superporous Hydrogel (SPH) polymer-based oral insulin delivery systems on plasma glucose in patients with type 1 diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
inclusion criteria: type1 diabetes, age of 17 - 45 years and the BMI levels ≥19 and ≤ 27 kg/m2. Exclusion criteria : any significant GI symptoms, previous hypersensitivity to polymer, clinically diagnosed diabetic gastroparesia, C-peptide> 0.5 ng/dl, forcing patients to use drugs intervention with insulin during study (LHRH agonists, cimetidine, ranitidine, quinolones, estrogen, diuretics, glucocorticoids, ß blockers, somatostatins, pegvisomant, thiazolidinediones and herbal medicines), history of GI bleeding, history of uncontrolled thyroid disease, history of acute febrile illness, history of blood donate in the past 3 months, psychological disease, cardiac disease.
Age
From **17 years** old to **45 years** old
Gender
Both

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **15**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Endocrine and Metabolism Research Centre (EMRC) ethics committee
Street address
5th floor, shariati hospital,North Karegar Ave, Tehran
City
Tehran
Postal code
Approval date
2009-05-21, 1388/02/31
Ethics committee reference number
E-0013

Health conditions studied

1

Description of health condition studied
Dibetes mellitus
ICD-10 code
E10
ICD-10 code description
insulin-dependent diabetes mellitus

Primary outcomes

1

Description
plasma insulin
Timepoint
At injection visit, 0(immediately before dosing), 5, 15, 30 (immediately before the meal), 60, 90, 120, 180, 240, and 360 min ; and at oral capsule visit, 0 (immediately before dosing), 30, 60, 120, 150, 180 (immediately before the meal), 210, 240, 300, 360 min
Method of measurement
blood sampling with ELISA kits (DiaMetra, Milano, Italy) for insulin

Secondary outcomes

1

Description
blood suger
Timepoint
At injection visit, 0 (immediately before dosing), 5, 15, 30 (immediately before the meal), 60, 90, 120, 180, 240, and360min; and at oral capsule visit, 0 (immediately before dosing), 30, 60, 120, 150, 180 (immediately before the meal), 210, 240, 300, 360 min
Method of measurement
blood sampling with enzymatic assay (Pars Azmoon, Iran)

Intervention groups

1

Description
Oral insulin- inside polymer capsule-800 U - consumed once
Category
Treatment - Drugs

2

Description
Placebo-oral capsule with polymer, without insulin - consumed once
Category
Placebo

3

Description
Oral insulin -1600 U outside polymer capsule - consumed once
Category
Treatment - Drugs

4

Description
Oral insulin -800 U - outside polymer capsule - consumed once
Category
Treatment - Drugs

5

Description
Subcutaneous injection of insulin 0.1 unit/kg and is injected once.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrinology and Metabolism Research Center
Full name of responsible person
Dr. Bagher Larijani
Street address
5th floor,shariati hospital, North Karegar Ave,
City
tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Endocrinology and Metabolism Research Center
Full name of responsible person
Dr. Bagher Larijani
Street address
5th floor,shariati hospital, North Karegar Ave
City
tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Endocrinology and Metabolism Research Center
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact
Name of organization / entity
Endocrinology and Metabolism Research Center, Tehran University of Medical Sciences
Full name of responsible person
Dr. Bagher Larijani
Position
Professor of Endocrinology and Metabolism
Other areas of specialty/work
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5th floor, Shariati hospital,North Karegar Ave
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tehran
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1411413137
Phone
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Fax
Email
emrc@tums.ac.ir
Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty