

Metabolic changes in obese patients with diabetes mellitus - impact of weight reduction

First published: 27/01/2015

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Study

Finalised

Administrative details

EU PAS number

EUPAS8455

Study ID

8456

DARWIN EU® study

No

Study countries

 Czechia

Study description

We estimated metabolic parameters of obese type 1 diabetics and compared them with subgroup of lean patients with diabetes mellitus type 1. We characterised the dynamic of metabolic parameters in obese type 1 diabetics during our weight reduction programme with acute and chronic phase of weight reduction. Measurements were done before (Phase I), after a month (Phase II) (one week of fasting in the hospital setting and three weeks on a diet containing 150g saccharides per day) and after one year (Phase III) on a diet with 225g saccharides per day. The main observed characteristics were: anthropometry, body composition, diabetes compensation, insulin resistance, markers of cholesterol metabolism, adipokines.

Study status

Finalised

Research institutions and networks

Institutions

University Hospital Hradec Králové

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jana Lesna

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/08/2008

Actual: 18/08/2008

Study start date

Planned: 02/02/2009

Actual: 04/02/2008

Data analysis start date

Planned: 04/08/2009

Actual: 05/05/2009

Date of final study report

Planned: 06/02/2012

Actual: 06/02/2012

Sources of funding

- Other

More details on funding

University Hospital in Hradec Kralove, MH CZ-DRO (UHHK, 00179906)

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Clinical trial

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

Obesity has become a serious problem among type 1 diabetics. These patients create an interesting subgroup with combination of metabolic disorders - absolute insulin lack and increased insulin resistance. Insulin resistance has been well characterised in obese patients with diabetes mellitus type 2, the subgroup of obese diabetics type 1 needs further research in lipid metabolism.

Study Design

Clinical trial regulatory scope

Pre-authorisation clinical trial

Clinical trial phase

Human pharmacology (Phase I)

Therapeutic exploratory (Phase II)

Therapeutic confirmatory (Phase III)

Study drug and medical condition

Medical condition to be studied

Diabetes mellitus management

Population studied

Short description of the study population

Obese and non-obese patients with diabetes mellitus type 1, and obese patients with diabetes mellitus type 2.

Age groups

- Adults (18 to < 46 years)
 - Adults (46 to < 65 years)
 - Adults (65 to < 75 years)
-

Special population of interest

Other

Special population of interest, other

Diabetes mellitus patients

Estimated number of subjects

50

Study design details

Data analysis plan

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Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No