The effects of 5-aminoimidazole-4-carboxamide ribonucleoside (AICAR) infusion in type two diabetes patients

Submission date	Recruitment status	Prospectively registered
09/06/2008	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
13/06/2008	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
30/12/2020	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

The effects of intravenous 5-aminoimidazole-4-carboxamide ribonucleoside (AICAR) infusion on glucose and fat metabolism in type two diabetes

Study objectives

To determine the impact of intravenous 5-aminoimidazole-4-carboxamide ribonucleoside (AICAR) administration on plasma glucose and fatty acid kinetics and skeletal muscle adenosine monophosphate (AMP)-activated protein kinase (AMPK) activation in vivo in type two diabetes patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Medical Ethical Committee of the Radboud University Nijmegen Medical Centre (Nijmegen, The Netherlands) in May 2006 (ref: 2005/262).

Study design

Single-blinded randomised trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Type two diabetes mellitus

Interventions

Each subject participates in two experimental tests; one test in which AICAR (0.75 mg/kg/min) is infused and one test in which only saline (0.9% NaCl) is infused to ensure equal volume administration. The trial consists of two test days separated by at least two weeks to allow washout. After 90 minutes of saline infusion, AICAR infusion was started for 120 minutes (so total duration of the infusion/day = 210 minutes). In the other test, no AICAR was infused, only saline. The order of the tests is randomised.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

5-aminoimidazole-4-carboxamide ribonucleoside (AICAR) infusion

Primary outcome measure

Tracer kinetics (rate of appearance and rate of disappearance) of glucose and free fatty acids. During both test days, outcomes were measured at the following timepoints: t = 0, 30, 45, 60, 75, 90, 105, 120, 135, 150, 165, 180, 195 and 210 minutes.

Secondary outcome measures

Plasma concentrations of:

- 1. Glucose
- 2. Free fatty acids (FFA)
- 3. Insulin
- 4. Lactate
- 5. Triglycerides
- 6. Free glycerol

During both test days, outcomes were measured at the following timepoints: t = 0, 30, 45, 60, 75, 90, 105, 120, 135, 150, 165, 180, 195 and 210 minutes.

Overall study start date

01/06/2006

Completion date

01/04/2007

Eligibility

Key inclusion criteria

- 1. Type two diabetes patients
- 2. Male
- 3. Aged 45 65 years

Participant type(s)

Patient

Age group

Adult

Sex

Male

Target number of participants

10

Total final enrolment

10

Key exclusion criteria

- 1. Renal or liver dysfunction
- 2. Gout
- 3. Exogenous insulin therapy

Date of first enrolment

01/06/2006

Date of final enrolment

01/04/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Maastricht University

Maastricht Netherlands 6229 ER

Sponsor information

Organisation

The Dutch Diabetes Research Foundation (The Netherlands)

Sponsor details

Division of Research Stationsplein 139 Amersfoort Netherlands 3818 LE

research@diabetesfonds.nl

Sponsor type

Research organisation

Website

http://www.diabetesfonds.nl/

ROR

https://ror.org/04ch2g225

Funder(s)

Funder type

Research organisation

Funder Name

The Dutch Diabetes Research Foundation (The Netherlands) (ref: 2002.00.004)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2008	30/12/2020	Yes	No