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

Submission date 09/06/2008	**Recruitment status** No longer recruiting
Registration date 13/06/2008	**Overall study status** Completed
Last Edited 30/12/2020	**Condition category** Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 wash-out. 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
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3818 LE
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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