

A randomised clinical trial of fludrocortisone for the prevention of vasovagal syncope

Submission date 04/11/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 23/06/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/02/2019	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.faintingresearch.ca>

Contact information

Type(s)

Scientific

Contact name

Dr Robert Stanley Sheldon

Contact details

Faculty of Medicine
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3330 Hospital Drive NW
Calgary, Alberta
Canada
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00118482

Secondary identifying numbers

Study information

Scientific Title

A randomised clinical trial of fludrocortisone for the prevention of vasovagal syncope

Acronym

POST II

Study objectives

Fludrocortisone prevents recurrences of vasovagal syncope.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Yes, November 2004, October 2005 and October 2006

Study design

Double-blind placebo-controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Patient information can be found on the website at <http://www.faintingresearch.ca/>

Health condition(s) or problem(s) studied

Vasovagal syncope

Interventions

Double-blind, placebo-controlled trial of fludrocortisone.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Fludrocortisone

Primary outcome measure

Time to first recurrence of syncope

Secondary outcome measures

1. The frequency of syncope
2. Pre-syncope frequency duration and intensity
3. Quality of life

Overall study start date

01/06/2005

Completion date

31/12/2009

Eligibility

Key inclusion criteria

Children (greater than 13 years) and adults, either sex, with greater than two lifetime episodes of vasovagal syncope.

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

310

Key exclusion criteria

1. Other causes of syncope, such as ventricular tachycardia, complete heart block, postural (orthostatic) hypotension or hypersensitive carotid sinus syndrome
2. An inability to give informed consent
3. Important valvular, coronary, myocardial or conduction abnormality or significant arrhythmia
4. Hypertrophic cardiomyopathy
5. A known intolerance to fludrocortisone
6. Another clinical need for fludrocortisone that can not be met with other drugs
7. A permanent pacemaker
8. A seizure disorder
9. A major chronic non-cardiovascular disease
10. Hypertension (blood pressure more than or equal to 130/85 on two occasions) or heart failure
11. Renal dysfunction (baseline glomerular filtration rate reduced below 60 ml/min/1.73m² according to the Cockcroft-Gault formula)
12. Diabetes mellitus

- 13. Hepatic disease
- 14. Glaucoma
- 15. Any prior use of fludrocortisone acetate
- 16. A five-minute stand test resulting in diagnosis of postural orthostatic tachycardia syndrome or orthostatic hypotension

Date of first enrolment

01/06/2005

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

Canada

Study participating centre

University of Calgary

Calgary, Alberta

Canada

T2N 4N1

Sponsor information

Organisation

University of Calgary (Canada)

Sponsor details

Faculty of Medicine

University of Calgary

3330 Hospital Drive NW

Calgary, Alberta

Canada

T2N 4N1

Sponsor type

University/education

Website

<http://www.ucalgary.ca/>

ROR

<https://ror.org/03yjb2x39>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: 130312)

Alternative Name(s)

Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Canada

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?
Protocol article	protocol	01/06/2006		Yes	No
Results article	results	05/07/2016	14/02/2019	Yes	No