

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

Submission date 04/11/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 23/06/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 14/02/2019	Condition category Signs and Symptoms	☐ 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

ClinicalTrials.gov (NCT)
NCT00118482

Protocol serial number
130312

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

Primary study design

Interventional

Study design

Double-blind placebo-controlled trial

Study type(s)

Prevention

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(s)

Time to first recurrence of syncope

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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)

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, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/07/2016	14/02/2019	Yes	No
Protocol article	protocol	01/06/2006		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes