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

Submission date 04/11/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/06/2005	**Overall study status** Completed	
Last Edited 14/02/2019	**Condition category** Signs and Symptoms	

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

Study design
Double-blind placebo-controlled trial

Primary study design
Interventional

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/1.73m^2 according to the Cockroft-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, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, 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