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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

Study website
http://www.faintingresearch.ca

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00118482

Secondary identifying numbers

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

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/1.73m^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)

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