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Fluid restriction versus no active treatment in chronic SIAD

Submission date
03/04/2018

Recruitment status
No longer recruiting

Registration date
27/04/2018

Overall study status
Completed

Last Edited
05/08/2021

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Up to 30% of patients admitted to hospital are found to have low sodium levels in their blood – a condition called hyponatremia. The most common cause is the syndrome of inappropriate antidiuresis (SIAD). SIAD occurs when levels of a hormone called vasopressin are higher than they should be. Causes include lung disease, brain injuries and medications. In some cases, no cause for SIAD is found. Many patients with low sodium due to SIAD feel they have no symptoms, especially if the problem is longstanding. However, low plasma sodium can cause subtle problems with balance and bone health.
At present, the treatment options for SIAD are not ideal and often ineffective. The recommended treatment for SIAD is to limit the amount of fluid a person takes per day – this is called fluid restriction. This can prove difficult for some patients, especially in the long-term and there is no reliable evidence from research studies to support its use. Up to one in five patients with low plasma sodium do not receive treatment in hospital aimed at their sodium. Often, these patients do as well as those who were treated with fluid restriction.
This study aims to determine if fluid restriction is any better than doing nothing in terms of correcting plasma sodium.

Who can participate?
Adults aged over 18 years with chronic hyponatraemia

What does the study involve?
Participants are randomly allocated to either no treatment or fluid restriction for a period of 30 days. Participants self-report their fluid intake, and are met 5 - 6 times during this period, during which time they have blood samples taken for sodium measurement. On the first and final visit, they are asked to complete a questionnaire and to walk across a gait analysis mat.

What are the possible benefits and risks of participating?
There are no direct benefits for participants taking part in the study.
Participants may be at risk of their sodium level falling further and developing symptoms such as headache or nausea. For this reason, participants are monitored regularly – after three days, one week and then two weeks. If sodium level falls and/or the participants develop symptoms they are treated with the appropriate treatment regardless of the study.

Where is the study run from?
Beaumont Hospital (Ireland)

When is the study starting and how long is it expected to run for?
January 2018 to October 2020 (updated 04/09/2019, previously: January 2020)

Who is funding the study?
Beaumont Hospital Endocrinology Research Fund (Ireland)

Who is the main contact?
Prof Chris Thompson (Scientific)

Contact information

Type(s)
Scientific

Contact name
Prof Chris Thompson

Contact details
Academic Department of Endocrinology / RCSI
Beaumont Hospital
Dublin
Ireland
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
A prospective randomised controlled trial comparing the effects of fluid restriction with no active hyponatremia treatment on rate of change of plasma sodium, and markers of hyponatraemia related morbidity, in patients with chronic hyponatremia due to the syndrome of inappropriate antidiuresis.

Study objectives
No active hyponatraemia treatment is non-inferior to fluid restriction in correcting hyponatraemia in chronic SIAD

Ethics approval required
Old ethics approval format

Ethics approval(s)
Beaumont Hospital Research Ethics Committee, 26/03/2018, ref: REC REF 18/04

Study design
Prospective unblinded randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
Chronic asymptomatic syndrome of inappropriate antidiuresis (SIAD)

Interventions
Once informed consent is acquired, participants are randomised to either fluid restriction or no active hyponatraemia treatment using a computer generated randomisation schedule using permutated blocks of four.
Participants randomised to fluid restriction are instructed to limit total fluid intake to 1 litre per 24 hours. Those randomised to no active treatment should continue to drink as usual. Fluid intake is self-reported. The intervention period is 30 days. Participants are assessed at day 1, 4, 11, 18 and 30, including medication check, documenting fluid intake records and blood sampling.

Intervention Type
Behavioural

Primary outcome measure
Plasma sodium is measured from a blood sample at baseline, 4 days and 30 days

Secondary outcome measures
1. Percentage of patients achieving a rise in plasma sodium > 5 mmol/L is assessed from a blood sample at days 4 and 30.
2. Percentage of patients achieving a plasma sodium > 130 mmol/L is assessed from a blood sample at days 4 and 30.
3. Length of hospital stay (if applicable) is assessed using the hospital record system at day 30.
4. Plasma sodium at time of hospital discharge (if applicable) is assessed using the hospital laboratory record system.

5. Urinary sodium, potassium and osmolality in those with treatment failure versus those who achieve above treatment thresholds is assessed from urine sample taken at baseline.
6. Mental and physical well-being is assessed using SF12 questionnaire at baseline and after 1 month.
7. Balance is assessed using the FootScan analysis mat at baseline and after 1 month.

Overall study start date
01/01/2018

Completion date
31/01/2020

Eligibility

Key inclusion criteria
1. Age > 18 years
2. Chronic hyponatraemia with plasma sodium 120 - 130 mmol/L
3. Euvolemia and biochemical confirmation of SIAD.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
56

Total final enrolment
46

Key exclusion criteria
1. Symptomatic hyponatraemia
2. Plasma sodium < 120 mmol/L
3. An underlying cause for hyponatraemia is recognised which is temporary or rapidly reversible with treatment of the underlying condition or removal of the causative medication
4. Hypo- or hyper-volemia
5. Diuretic therapy
6. Uncontrolled hyperglycaemia (blood glucose > 16.6 mmol/L)
7. Pregnancy

Date of first enrolment
01/05/2018

Date of final enrolment
31/01/2020

Locations

Countries of recruitment
Ireland

Study participating centre
Beaumont Hospital
Beaumont Road
Dublin
Ireland
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Sponsor information

Organisation
Beaumont Hospital

Sponsor details
Academic Department of Endocrinology / RCSI
Beaumont Hospital
Dublin
Ireland
9

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/043mzjj67

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Beaumont Hospital Endocrinology Research Fund

Results and Publications

Publication and dissemination plan
Plans to publish in peer-reviewed journal.

Intention to publish date
01/01/2021

Individual participant data (IPD) sharing plan
Participant level data generated in this study will be available on request from Professor Chris Thompson (principal investigator). Data will be coded, and stored on the hospital secure electronic database.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2020	05/08/2021	Yes	No