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Analysis of water and electrolyte balance during osmotherapy in meningitis/encephalitis

Submission date
11/03/2017

Recruitment status
No longer recruiting

Registration date
04/04/2017

Overall study status
Completed

Last Edited
18/02/2022

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Tick-born encephalitis virus (TBEV) is an infectious viral disease that is spread to humans by a bite from a small bug called a tick. TBEV is rare but occurs in some European and Asian countries. It can become very serious if the virus spreads to the brain (causing encephalitis (swelling of the brain)) or to the tissue that covers the brain and spinal cord (causing meningitis). The symptoms of TBEV can be classified by phases. The first phase of symptoms occur one month after a tick bite and can include headaches, vertigo (a feeling that everything around you is moving or spinning), joint and muscle pain. After these symptoms, most people can make a complete recovery. However, some patients may experience a second phase of symptoms which include fever, headaches, neck stiffness, seizures, sensitivity to light, paralysis (unable to move body parts), confusion, drowsiness or disorientation. These symptoms are very serious and usually require hospitalization. In order to help lower the levels of pressure on the brain, Mannitol is usually given to patients. Mannitol is a diuretic which promotes urination (peeing) in order to get rid of extra fluids and salt in the body. However, Mannitol can lead to dangerously low water levels in the body as it lowers the levels of electrolytes (salts) in the body. Therefore, treating TBEV with Mannitol requires monitoring of the patient's water and electrolyte levels. The aim of this study is assess the influence of one dose of 15% Mannitol on patient's hydration (water levels).

Who can participate?
Adults aged 18 and older who are diagnosed with meningitis/encephalitis.

What does the study involve?
Participants receive the standard 0.25g/kg 15% dose of Mannitol (given through a needle in the arm) as treatment for meningitis/encephalitis. Participants have blood samples taken prior to the dose of Mannitol and one hour after receiving the Mannitol dose. The blood samples are measured for electrolyte levels. Participants also are measured for their hydration before the Mannitol dose and one after the dose using a whole body scan. This measures the water levels in the body. Participants undergo the standard hospitalisation period and are followed up with out-patient visits for six months.

What are the possible benefits and risks of participating?
There are no notable benefits or risks with participating.

Where is the study run from?
Medical University in Białystok (Poland)

When is the study starting and how long is it expected to run for?
July 2016 to December 2019

Who is funding the study?
Medical University Białystok (Poland)

Who is the main contact?
Dr Piotr Czupryna

Contact information

Type(s)
Scientific

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Type(s)
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1/2017

Study information

Scientific Title
Assessment of one dose Mannitol influence on hydration and electrolytes concentration in patients with viral meningitis

Acronym
MICHA

Study objectives
Mannitol significantly influences on patients hydration and electrolyte balance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee by Medical University of Bialystok, 28/05/2015, ref: R-I-002/214/2015

Study design
Observational single-centre case series study

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Tick-borne encephalitis/meningitis

Interventions

All patients with meningitis/encephalitis receive Mannitol as a standard treatment. However, participants in this trial are monitored more closely for potential water and electrolytes balance in order to properly adjust the supplmentation.

Participants are treated with a 0.25 g/kg 15% Mannitol dose given intravenously. In all participants, electrolyte (Na, K, Cl) and creatinine concentrations are measured using blood tests. The first blood sample is taken before the first dose of Mannitol. A second blood sample is taken one hour after the Mannitol administration.

Participants hydration status is measured before and one hour after Mannitol implementation by whole body bioelectrical impedance with multiple frequency equipment (BodyStat QuadScan 4000). The parameters that are analysed are: Total Body Water volume (TBW) in liters and percent of body mass, Internal Body Water volume (IBW) in liters and percent of body mass, External Body Water volume (EBW) in liters and percent of body mass, third space body water.

Participants undergo the standard observation period of patients with meningitis/encephalitis (two weeks of hospitalization) and are followed-up according to the standard level of care for six months with periodic visits to the Out-Patients Department.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Mannitol

Primary outcome measure
1. Hydration status is measured using whole body bioelectrical impedance with multiple frequency equipment BodyStat QuadScan 4000 at baseline and one hour
2. Electrolyte concentration in blood is analyzed in the hospital laboratory in accordance with standardized methodology at baseline and one hour

Secondary outcome measures
1. Total Body Water volume (TBW) is measured using whole body bioelectrical impedance with multiple frequency equipment BodyStat QuadScan 4000 at baseline and one hour
2. Internal body water volume is measured using whole body bioelectrical impedance with multiple frequency equipment BodyStat QuadScan 4000 at baseline and one hour
3. External Body water volume is measured using whole body bioelectrical impedance with multiple frequency equipment BodyStat QuadScan 4000 at baseline and one hour
4. Third space body water and electrolytes concentration is measures using whole body bioelectrical impedance with multiple frequency equipment BodyStat QuadScan 4000 at baseline and one hour

Overall study start date
01/08/2016

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Adults aged 18 years old and older
2. Hospitalised due to tick-borne encephalitis in the Department of Infectious Diseases and Neuroinfections Medical University in Bialystok
3. Tick-borne encephalitis diagnosed based on clinical picture, cerebrospinal fluid (CSF) examination and specific antibodies presence in serum and TBE antibodies titer measured with Enzygnost Anti-TBE/FSME Virus (IgG, IgM) Siemens test

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
Lack of agreement to study terms

Date of first enrolment
01/08/2016

Date of final enrolment
01/08/2019

Locations

Countries of recruitment
Poland

Study participating centre
Medical University in Białystok
Department of Infectious Diseases and Neuroinfections
Zurawia 14
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Sponsor information

Organisation
Medical University Białystok

Sponsor details
Jana Kilinskiego 1
Bialystok
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15089

Sponsor type
University/education

Website
www.umb.edu.pl

ROR
https://ror.org/00y4ya841

Funder(s)

Funder type
University/education

Funder Name
Medical University Białystok

Results and Publications

Publication and dissemination plan
Preliminary results are planned to be published and final results are planned to be published in a high-impact peer reviewed journal.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Piotr Czupryna; email: avalon-5@wp.pl

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		20/03/2017	04/04/2017	No	Yes
Results article		20/08/2018	18/02/2022	Yes	No