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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

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

### Contact name
Dr Piotr Czupryna

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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 hypothesis
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

### Condition
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

## Overall study end date
31/12/2019

# Eligibility

### Participant 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

### Participant exclusion criteria
Lack of agreement to study terms

### Recruitment start date
01/08/2016

### Recruitment end date
01/08/2019

# Locations

### Countries of recruitment
Poland

### Study participating centre
**Medical University in Białystok**
Department of Infectious Diseases and Neuroinfections
Zurawia 14
Bialystok
Poland
15540

# Sponsor information

**Organisation**
Medical University Białystok

**Sponsor details**
Jana Kilinskiego 1
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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 |