# Intravenous dexamethasone in acute management of vestibular neuronitis

Submission date	Recruitment status No longer recruiting	Prospectively registered		
22/12/2010		☐ Protocol		
Registration date 31/03/2011	Overall study status Completed Condition category	Statistical analysis plan		
		[X] Results		
Last Edited		[] Individual participant data		
18/01/2019	Ear, Nose and Throat			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

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# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

VN001

# Study information

#### Scientific Title

Intravenous dexamethasone in acute management of vestibular neuronitis: a prospective single centre randomised placebo controlled trial

## **Study objectives**

Intravenous administration of dexamethasone in combination with vestibular suppressant (diazepam) and antiemetic (thiethylperazine) leads to a quicker recovery of clinical symptoms in patients with vestibular neuronitis (VN) when compared to administration of vestibular suppressant (diazepam) and antiemetic (thiethylperazine).

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

University Hospital Centre Zagreb Ethical Committee approved on the 29th November 2010

#### Study design

Prospective single centre randomised placebo 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, please use the contact details below to request a patient information sheet

# Health condition(s) or problem(s) studied

Vestibular neuronitis

#### **Interventions**

All patients who are diagnosed as VN and have signed informative consent forms will be randomised in one of two groups (A or B):

- 1. Patients in group A will receive dexamethasone 12 mg intravenous (i.v.), diazepam 10 mg in 500 ml saline and thiethylperazine 10 mg subcutaneously (s.c.)
- 2. Patients in group B will receive placebo saline i.v., diazepam 10 mg in 500 ml saline and thiethylperazine 10 mg s.c.

The duration of treatment is one hour in the emergency department. Follow up is 4 hours in the emergency department, and there is follow up visit one month after.

#### Intervention Type

Drug

#### Phase

Not Applicable

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

Dexamethasone, diazepam, thiethylperazine

#### Primary outcome measure

Necessity to hospitalise patients who present with VN in the emergency department.

All outcomes will be measured at the admittance to the emergency department and 120 mins after the treatment.

#### Secondary outcome measures

- 1. Improvement of nystagmus (grading by Alexander)
- 2. Improvement of postural instability (grading by Fukuda test)
- 3. Lessening of nausea (according of visual-analog scale)
- 4. Lessening of vomiting
- 5. Recovery of subjective symptoms (according to European Evaluation of Vertigo scale)

All outcomes will be measured at the admittance to the emergency department and 120 mins after the treatment.

#### Overall study start date

15/01/2011

# Completion date

15/01/2013

# **Eligibility**

#### Kev inclusion criteria

Patients older than 18 years of age (either sex) who will be diagnosed as vestibular neuronitis in the emergency neurology department based on the following criteria:

- 1. Persistent rotatory vertigo which started up to 48 hours
- 2. Horisontal-torsional nystagmus, unidirectional, more pronounced on removing fixation
- 3. Positive head thrust test on the side of vestibular lesion
- 4. Absence of skew deviation (assessed by Maddox rod test)
- 5. Normal brain multi-slice computed tomography (MSCT)
- 6. Normal electrocardiogram (ECG)
- 7. Normal laboratory findings (complete blood count [CBC], prothrombin time [PT], activated partial thromboplastin time [APTT], blood glucose level, urea, creatinine, aspartate aminotransferase [AST], alanine aminotransferase [ALT], gamma-glutamyl transferase [GGT], creatine kinase [CK], lactate dehydrogenase [LD])

## Participant type(s)

Patient

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

### Target number of participants

100

# Key exclusion criteria

- 1. Loss of hearing
- 2. Tinnitus
- 3. Presence of any neurological deficit
- 4. Medical history containing data of:
- 4.1. Unregulated arterial hypertension
- 4.2. Atrial fibrillation
- 4.3. Diabetes mellitus
- 5. Patients taking:
- 5.1. Corticosteroids
- 5.2. Benzodiazepines
- 5.3. Patients who have contraindications for taking corticosteroids and benzodiazepines

#### Date of first enrolment

15/01/2011

#### Date of final enrolment

15/01/2013

# Locations

#### Countries of recruitment

Croatia

# Study participating centre Department of Neurology

Zagreb Croatia HR-10000

# Sponsor information

# Organisation

University Hospital Centre Zagreb (Croatia)

# Sponsor details

Department of Neurology Kispaticeva 12 Zagreb Croatia HR-10000

#### Sponsor type

Hospital/treatment centre

#### Website

http://www.kbc-zagreb.hr

#### **ROR**

https://ror.org/00r9vb833

# Funder(s)

#### Funder type

Hospital/treatment centre

#### **Funder Name**

University Hospital Centre Zagreb (Croatia) - Department of Neurology

# **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?
Results article	results	01/10/2016	18/01/2019	Yes	No