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Intravenous dexamethasone in acute management of vestibular neuronitis

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Key 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