ISRCTN84838161 https://doi.org/10.1186/ISRCTN84838161

Intravenous dexamethasone in acute management of vestibular neuronitis

Submission date	Recruitment status	[_] Prospectively registered
22/12/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/03/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] 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
Dr Mario Habek

Contact details
Department of Neurology
Zagreb Medical School and University Hospital Centre
Kispaticeva 12
Zagreb
Croatia
HR-10000
+385 (0)1 237 6033
mhabek@mef.hr

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

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

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