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Prophylactic treatment of vestibular migraine with metoprolol

Submission date	Recruitment status	[X] Prospectively registered
07/07/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/08/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/02/2018	Nervous System Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A vestibular migraine is a nervous system problem that causes repeated dizziness (or vertigo). The attacks of vertigo can be associated with headaches and other migraine-typical symptoms such as need for rest, and sensitivity to light and/or noise. Most patients additionally suffer from migraine with or without aura. The diagnosis of patients with vestibular migraine is usually based on the typical medical history and response to drug treatment. The preventative treatment of vestibular migraine corresponds to the treatment of migraine with aura, but its effectiveness for vestibular migraine has not yet been proven. The aim of this study is to review this treatment method.

Who can participate?
Patients aged 18 to 80 with vestibular migraine

What does the study involve?
Participants are randomly allocated to receive the drug metoprolol or a placebo (dummy) treatment for 6 months. During the 6-month treatment, four examination appointments and three telephone interviews take place, as well as a follow-up appointment 3 months after stopping the medication. All examination appointments take place on an outpatient basis. The number of vertigo attacks and number of migraine attacks are compared in the two treatment groups during the last 3 months of the 6-month treatment period.

What are the possible benefits and risks of participating?
During the study, participants receive care that exceeds the level of usual care. Measurements are painless. The drug metoprolol (beta-blocker) has been well-known for many years and is widely and successfully used in both conventional migraine and cardiovascular (heart) diseases. The risk of serious or unknown side effects is therefore low, especially in the placebo group. Costs for the journey to the outpatient examination will be refunded.

Where is the study run from?
1. University Medical Center München (Germany)
2. Medical Center Celle (Germany)
3. Medical Center Altötting (Germany)

4. University Medical Center Tübingen (Germany)
5. University Medical Center Essen (Germany)
6. Medical Center Parkklinik Weißensee, Berlin (Germany)

When is the study starting and how long is it expected to run for?
January 2010 to October 2019

Who is funding the study?
Federal Ministry of Education and Research (BMBF) (Germany)

Who is the main contact?
Prof. Michael Strupp

Study website
http://ifb.klinikum.uni-muenchen.de/de/Studienzentrum/PROVEMIG_Studie/index.html

Contact information

Type(s)
Scientific

Contact name
Prof Michael Strupp

Contact details
Marchioninistr. 15
Munich
Germany
81377

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DRKS00005040; VMMET009

Study information

Scientific Title
Prophylactic treatment of vestibular migraine with metoprolol: a double-blind, placebo-controlled trial

Acronym
PROVEMIG

Study objectives
Metoprolol (95 mg per day) is more effective in reducing the number of vertigo attacks and headache attacks in vestibular migraine than placebo.

Further details can be found at: http://drks-neu.uniklinik-freiburg.de/drks_web/navigate.do?navigationId=trial.HTML&TRIAL_ID=DRKS00005040 and http://ifb.klinikum.uni-muenchen.de/de/Studienzentrum/PROVEMIG_Studie/index.html

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Commitee of the Ludwig-Maximilians-University, pending as of 09/07/2009

Study design
Multicentre national randomised double-masked placebo-controlled two-arm parallel-group efficacy of treatment study

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Vestibular migraine

Interventions
The trial comprises of two arms:
1. Therapy with metoprolol 95 mg per day
2. Placebo

The total treatment time will be six months with a three month follow-up. The trial is estimated to last four years (first patient in to last patient out).

Intervention Type
Drug

Phase
Phase III

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

Primary outcome measure
The number of vertigo attacks and number of migraine attacks during the last 3 months of the 6-month treatment period

Secondary outcome measures
1. Number of vertigo attacks during the last 3 months of the total follow-up period of 9 months
2. Median duration and severity of vertigo attacks during the last 3 months of the 6-month treatment period and the last 3 months of the total follow-up period
3. Number of headache days per month during the last 3 months of the 6-month treatment period and the last 3 months of the total follow-up period
4. Change of peripheral vestibular function and handicap/impairment due to vertigo between baseline, 6-month visit and 9-month visit

Overall study start date
01/01/2010

Completion date
01/10/2019

Eligibility

Key inclusion criteria
1. Diagnosis of definite vestibular migraine according to the criteria of Neuhauser et al. 2001:
1.1. Episodic vestibular symptoms of at least moderate severity (rotational vertigo, other illusory self or object motion, positional vertigo, head motion intolerance, i.e., sensation of imbalance or illusory self or object motion that is provoked by head motion)
1.2. Migraine according to the International Headache Society (IHS) criteria
1.3. At least one of the following migrainous symptoms during at least two vertiginous attacks: migrainous headache, photophobia, phonophobia, visual or other auras
1.4. Other causes ruled out by appropriate investigations
2. At least two attacks per month for at least 3 subsequent months
3. Aged 18 to 80 years, either sex
4. Written informed consent, signed and dated by the patient (or patient's authorised representative) and by the person obtaining the consent, indicating agreement to comply with all protocol-specified procedures

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
260

Key exclusion criteria
1. Other vestibular disorders such as Meniere's disease, phobic postural vertigo, benign paroxysmal positioning vertigo, vestibular paroxysmia; central disorders such as paroxysmal brainstem attacks, transient ischaemic attacks (TIAs)
2. Contraindications for the treatment with metoprolol such as:
2.1. Known allergic reaction to one of the trial drugs
2.2. Pregnancy or breastfeeding
2.3. Sinoatrial (SA)-block, atrioventricular (AV)-block, sick sinus syndrome, bradycardia less than 50 bpm at rest, systolic blood pressure less than 100 mmHg, end-grade peripheral arterial disease, and bronchial asthma
2.4. Pheochromocytoma
2.5. Poorly controlled diabetes mellitus
2.6. Porphyria
2.7. Psoriasis
2.8. Disorders of haemostasis
2.9. Concurrent medications, such as monoamine oxidase (MAO)-inhibitor, sympathomimetic drugs
2.10. Known severe coronary heart disease or heart failure
2.11. Persistant hypertension with systolic blood pressure greater than 180 mmHg or diastolic BP greater than 110 mmHg (mean of three consecutive arm-cuff readings over 20 - 30 minutes) that cannot be controlled by anti-hypertensive therapy
2.12. Life expectancy less than 12 months
3. Other serious illness, e.g., severe hepatic, cardiac, or renal failure, acute myocardial infarction, neoplasm or a complex disease that may confound treatment assessment
4. Participation in another study with an investigational drug or device within the last 30 days, prior participation in the current study, or planned participation in another trial

Date of first enrolment
01/01/2010

Date of final enrolment
01/07/2018

Locations

Countries of recruitment
Germany

Study participating centre
University Medical Center München
Germany
-

Study participating centre
Medical Center Celle
Germany
-

Study participating centre
Medical Center Altötting
Germany
-

Study participating centre
University Medical Center Tübingen
Germany
-

Study participating centre
University Medical Center Essen
Germany
-

Study participating centre
Medical Center Parkklinik Weißensee, Berlin
Germany
-

Sponsor information

Organisation
Klinikum Grosshadern (Germany)

Sponsor details
Ludwig Maximilians University of Munich
Marchioninistr. 15
Munich
Germany
81377

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05591te55

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung - Integrated Research and Treatment Centre (IFB)

Alternative Name(s)
Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

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