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Comparison of ambulatory and in-patient Multiple Sleep Latency Test (MSLT) - validation of the ambulatory version, assessment of interrater variability of these sleep studies and economic evaluation

Submission date	Recruitment status	[X] Prospectively registered
02/12/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/01/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/01/2011	Nervous System Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Comparison of ambulatory and in-patient Multiple Sleep Latency Test (MSLT) - validation of the ambulatory version, assessment of interrater variability of these sleep studies and economic evaluation: a randomised single-blind crossover study in 50 patients with complaints of excessive daytime sleepiness or clinical suspicion of narcolepsy

Study objectives
Consecutive patients referred to Akershus University Hospital, Section for Clinical Neurophysiology, with complaints of excessive daytime sleepiness or clinical suspicion of narcolepsy will be randomised to either perfom the ambulatory or in-patient Multiple Sleep Latency Test (MSLT) first and then a week later perform the opposite set-up (randomised cross-over trial). The validity of ambulatory MSLT (together with a previous night polysomnogram [PSG]) will be assessed by comparing average sleep latency, number of SOREM-positive tests and sleep efficiency in the AHUS aMSLT to those derived from the inpatient MSLT protocol recommended by American Academy of Sleep Medicine (AASM). Using data from this study we will also analyse the difference in the economic burden to the hospital regarding out-patient versus in-house patient sleep studies as well as inter-rater scoring reliability.

Hypothesis:
There is no significant difference between performing ambulatory MSLT or in-patient MSLT with regards to measurements of average sleep latency and number of SOREM-positive tests.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South-East Regional Ethics Committee A in Norway approved on the 8th December 2008 (ref: S-08567a; Saksnummer: 2008/9477)

Study design
Randomised single-blind crossover study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hypersomnia, narcolepsy, excessive daytime sleepiness (EDS)

Interventions
Patients will be randomised to either perform the MSLT first as in-patients in accordance with the published and widely accepted AASM protocol (AASM 2005), or according to the ambulatory MSLT method.

We have no treatment in this study and no follow-up period. After the ambulatory and in-patient MSLTs are performed the results will be sent to the referring doctor for evaluation.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Average sleep latency
2. Number of SOREM (sleep onset REM)-positive tests
3. Inter-rater relibility with regards to these parameters for the MSLT
4. Assessment of inter-rater relibility with regards to the PSG (polysomnography) performed in conjunction with the MSLT

Primary and secondary outcomes will be measured immediately after the MSLT tests are performed. We will score the sleep studies using criteria from the American Academy of Sleep Medicine Manual for the Scoring of Sleep and Associated events (2007).

Key secondary outcome(s))
1. Recording problems (for example artefacts on the recordings)
2. How well patients adhere to sleeping schedules
3. Sleep efficiency and PLM (periodic leg movement) as evaluated from the PSG
4. Patients sleep log recordings on the day and night of the recordings
5. Epworth sleepiness scale
6. Karolinska sleep questionnaire
7. Global Sleep Assessment Questionnaire
8. EQ-5D (fra Euroqol-gruppen)

Primary and secondary outcomes will be measured immediately after the MSLT tests are performed. We will score the sleep studies using criteria from the American Academy of Sleep Medicine Manual for the Scoring of Sleep and Associated events (2007).

Completion date
01/08/2012

Eligibility

Key inclusion criteria
Patients aged between 18 and 65 years (inclusive), either sex, referred to a sleep study due to excessive daytime sleepiness or clinical suspicion of narcolepsi

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

All

Key exclusion criteria
1. Patients under 18 years of age
2. Patients older than 65 years of age

Date of first enrolment
01/02/2011

Date of final enrolment
01/08/2012

Locations

Countries of recruitment
Norway

Study participating centre
Sykehusveien 25
Nordbyhagen
Norway
1478

Sponsor information

Organisation
Akershus University Hospital (Norway)

ROR
https://ror.org/0331wat71

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Akershus University Hospital (Norway) - Department of Neurology

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration