

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 02/12/2010	Recruitment status No longer recruiting	☒ Prospectively registered
		☐ Protocol
Registration date 21/01/2011	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 21/01/2011	Condition category Nervous System Diseases	☐ Individual participant data
		☐ 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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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 perform the ambulatory or in-patient Multiple Sleep Latency Test (MSLT) first and then a week later perform the opposite set-up (randomised crossover 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)

Primary study design

Interventional

Study design

Randomised single-blind crossover study

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 reliability with regards to these parameters for the MSLT
4. Assessment of inter-rater reliability 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)

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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