

# 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

<b>Submission date</b> 02/12/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 21/01/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 21/01/2011	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Kornelia Katalin Beiske

**Contact details**  
Sykehusveien 25  
Nordbyhagen  
Norway  
1478

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 perform 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

### Secondary study design

Randomised controlled trial

### Study setting(s)

Other

### 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**

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 measure**

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).

**Secondary outcome measures**

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).

**Overall study start date**

01/02/2011

**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

## Age group

Adult

## Lower age limit

18 Years

## Sex

Both

## Target number of participants

50

## 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)

**Sponsor details**

Sykehusveien 25  
Nordbyhagen  
Norway  
1478

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.ahus.no/>

**ROR**

<https://ror.org/0331wat71>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Akershus University Hospital (Norway) - 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