Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of oral Midazolam, Clonidin and Melatonin with Chloral hydrate for recording sleep EEG in children

Protocol summary

Summary

Performing of diagnostic medical procedures needs patient's cooperation that children often refuse it. Although behavioral training could be successful in promoting Electroencephalography (EEG) compliance without restraint or sedation, EEG recording in children not amenable to behavioral training often requires sedation. Furthermore natural sleep and sleep deprivation increases the yield of seizure activity. In our EEG clinic, Chloral hydrate is being used routinely for recording sleep EEG, however its unpleasant taste and many side effects may warrant an alternative sedative for uncooperative children. In this study, we compare oral form of Clonidin, Melatonin and Midazolam with Chloral hydrate for sedation induction in 400 children aged: between 1 month to 72 months. Study outcomes included neurological diagnosis, sleep onset latency, sleep duration, drowsiness time and adverse drug events that may happen in the first 24 h after EEG. Drug effects on EEG background and yield of epileptic discharges is very important and we consider it; these finding will be recorded for future interpretation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106286907N1**
Registration date: **2011-10-01, 1390/07/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-10-01, 1390/07/09

Registrant information

Name

Mahmoudreza Ashrafi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-01-01, 1389/10/11

Expected recruitment end date

2012-01-01, 1390/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of oral Midazolam, Clonidin and Melatonin with Chloral hydrate for recording sleep EEG in children

Public title

Comparison of oral Midazolam, Clonidin and Melatonin with Chloral hydrate for recording sleep EEG in children

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria; non cooperative children aged between 1 month to 72 months and patients that refered for Sleep EEG. Exclusion criteria ; Hypersensensivity to Chloral hydrate, Melatonin, Midazolam and Clonidin; hepatic or renal diseases; severe cardiac disease; peptic ulcer; severe tonsillar or adenoid hypertrophy and being under treatment with medications that have serious interaction

with these drugs .

Age

To **6 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **400**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committe of Tehran University of Medical Sciences

Street address

Tehran-pour sina avenu-Tehran University of Medical Sciences

City

Tehran

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

90/130/956

Health conditions studied

1

Description of health condition studied

Induction of sedation for recording sleep EEG

ICD-10 code

G40.9

ICD-10 code description

Epilepsy, unspecified

Primary outcomes

1

Description

Time to sleep, Sleep duration and time to awakeness

Timepoint

Immediately after consumption

Method of measurement

Examination

Secondary outcomes

1

Description

Possible side effect of drugs

Timepoint

While treatment

Method of measurement

Questionaire

Intervention groups

1

Description

Midazolam prescribed as oral solution(Amsed oral liquid 2.5 mg in 1 ml) 0.5 mg/kg/dose .

Category

Treatment - Drugs

2

Description

Clonidin prescribed as tablet(0.2mg) 2-4 microgram/kg/dose .

Category

Treatment - Drugs

3

Description

Chloral hydrate prescribed as solution of 10% 1cc/kg/dose

Category

Treatment - Drugs

4

Description

Parents informed that to put their children to sleep 2 h later than the usual time , awaken them at 6.00 am and not to let them fall asleep until the time of EEG recording . Melatonin prescribed as Syrup (KidNaps oral liquid 1 mg in1ml) 2-6 mg/dose .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Children's Medical Center - EEG Department
Full name of responsible person
Dr. Firozeh Hosseini ,Fellowship of Child Neurology
Street address
Children's Medical Center, Dr Gharib Avenue
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Rostamabadi
Street address
Sixth floor, Central bulding of Tehran University of Medical Sciences
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

2

Sponsor
Name of organization / entity
Behinpad Company
Full name of responsible person
Dr Marjan Dibayan
Street address
No 505, Behrouz Street, Mirdamad avenue
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Behinpad Company
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mahmoudreza Ashrafi
Position
Professor Of Pediatric Neurology
Other areas of specialty/work
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1419733151
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Fax
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Email
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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty