Combined PSGand HRM-MII measurement to assess the relation between gastroesophageal reflux and apnea in infants

Published: 06-03-2013
Last updated: 23-04-2024

Determine the existence of a relation between GER and apnea and their underlying mechanisms, in infants *37 weeks * 12 months.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Observational invasive

Summary

ID

NL-OMON40182

Source
ToetsingOnline

Brief title
Relation between gastroesophageal reflux and apnea in infants

Condition

- Gastrointestinal motility and defaecation conditions
- Neonatal respiratory disorders

Synonym
cessation of breath/breathpauses, regurgitation/backflow of gastric contents into esophagus

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: apneas, gastro esophageal reflux, High resolution Manometry/, Polysomnography

Outcome measures

Primary outcome

Temporal relation between onset transient lower esophageal sphincter relaxations (TLESR), onset of GER event, onset of GER reaching the pharynx (if present), onset of cessation of nasal airflow, onset of cessation of respiratory effort (if present), onset of deceleration of heart rate(if present) and onset of desaturation(if present)

Secondary outcome

GERd complaints objectified through questionnaire parents

Study description

Background summary

Gastroesophageal reflux (GER) and apnea are two phenomena often seen in infants. GER is the involuntary movement of gastric contents into the esophagus. Pathologic GER (GER disease (GERD)) is defined as GER which causes troublesome symptoms or complications. An apneai is a cessation of respiratory air flow and might be central (no respiratory effort), obstructive (usually upper airway obstruction) or mixed in nature. Pathological apnea is defined as a cessation of breathing for >20 seconds, or a period of shorter duration accompanied with significant desaturation, hypoxemia or bradycardia. Since GER and apnea often coincide in infants, a causal relationship is commonly proposed. Several theories suggest GER to be a causal factor in the generation of both central and obstructive apnea*s, but vice versa apnea*s have been suggested to cause GER as well. Finally, both breathing an GER are centrally mediated in the same region of the brainstem and could thus both be the result of a single vagally mediated central phenomenon. There is a substantial number of studies conducted to assess these presumed relationships but no definite conclusions can be drawn as yet. This is most likely the result of these

studies, being of poor methodological quality and lacking a complete evaluation of gastroesophageal reflux and - function and/or evaluation of apnea.
A combined high-resolution manometry / high resolution multichannel intraluminal impedance (HRM-MII) and complete polysomnography(PSG) is the most sophisticated way to assess any relation between GER and apnea and their underlying mechanisms.

Study objective

Determine the existence of a relation between GER and apnea and their underlying mechanisms, in infants *37 weeks * 12 months.

Study design

prostpective, pathophysiological, observational study

Study burden and risks

All infants will undergo a combined HRM-MII for 6 hours during the 12 hour PSG study. The usual 24 hour clinical GER measurement is completed as per PSG protocol after the 6 hours, without the need of any additional hospital stay.

PSG recordings are non invasive and considered clinical necessary in the included infants. Per clinical PSG protocol, a standard 24 hour combined pH-MII measurement is included in the evaluation of the patient. For this purpose, infants are intubated with a 6 french gastroesophageal catheter. For the purpose of this study, this catheter will be replaced by a 6 french HRM-MII catheter for the first 6 hours of the study. In our experience, this procedure is well tolerated and causes only minor discomfort in infants. For correct placement of the pH-MII catheter, a thorax X-ray is made during clinical PSG studies. Our study catheter is able to exactly locate the position of the lower esophageal sphincter relative to the nose, making this X-ray unnecessary. All included patients will thus be spared radiation.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Informed consent signed by care-givers
*37wks * 12 months GA
Clinical suspicion of unexplained respiratory events, apneas and gastroesophageal reflux

Exclusion criteria

Previous gastro-intestinal (GI) surgery
Structural gastro intestinal abnormalities
Neurological Syndromes
Any condition that will make it unsafe the subject to participate.
medical treatment of GER and/or apneas < 3 days prior to study.
Any condition that will make discontinuation of medication impossible, as determined by the treating physician.

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-04-2013
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	06-03-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL43264.018.13