Paediatric and Adult Causes of Encephalitis and Meningitis: The PACEM study.

Published: 14-11-2011 Last updated: 29-04-2024

To evaluate the incidence, causes and characteristics of meningitis and/or encephalitis in patients of all ages:1. To determine the causes of meningitis and/or encephalitis in children and adults2. To evaluate the clinical signs and symptoms and CSF...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON35777

Source ToetsingOnline

Brief title PACEM-study

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Central nervous system infections and inflammations

Synonym brain-infection, meningo-encephalitis

Research involving Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum Source(s) of monetary or material Support: Ministerie van OC&W

1 - Paediatric and Adult Causes of Encephalitis and Meningitis: The PACEM study. 25-05-2025

Intervention

Keyword: encephalitis, etiology, infection, meningitis

Outcome measures

Primary outcome

1. Detection of viruses and other micro-organisms in CSF, blood, nasopharyngeal

aspirates and feces

2. Clinical signs and symptoms as defined as: headache, fever, irritability,

altered consciousness, seizures, etc in relation to cause

3. Cell count, protein and glucose level of CSF and relation with causative

organism

4. Death or permanent sequellae due to meningitis/encephalitis

Secondary outcome

1. Costs, duration of hospitalization and antibiotic use due to

meningitis/encephalitis

Study description

Background summary

Meningitis (inflammation of the meninges) and encephalitis (inflammation of the brain in association with clinical evidence of neurologic dysfunction) are potential life-threatening conditions that can rapidly progress to permanent brain damage, neurologic problems, and even death. Since vaccination against the most common causative bacteria (H. influenza type b, S. pneumonia, N. meningitidis serogroup C), the incidence of bacterial meningitis has dropped significantly. Therefore, non-bacterial pathogens, such as viruses and tick-born pathogens are increasingly recognized as important causes of central nervous system (CNS) infections. In addition, immune-mediated processes (like ADEM and antibody associated encephalitis) seem to play an important role. For example, in a study in the UK, immune mediated processes were found in 20 percent of patients with encephalitis.

In contrast with bacterial meningitis, for which an extensive surveillance system has been set up in many countries, viral or non-bacterial CNS infection is not monitored systematically and proper incidence numbers of the different causative agents and mortality and morbidity rates are missing. Recently it has been propagated that it is important to optimize the surveillance for viral encephalitis/meningitis in Europe to gain more insight in the aetiological pattern as well as to optimize therapy to improve survival and reduce brain injury.

The aim of this project is to set up a regional pilot survey study that will systematically register both clinical and laboratory findings of adults and children with meningitis and/or encephalitis in the Netherlands to gain more insight in the causes and pathogenesis of these diseases. After one year, the results of the pilot survey will be evaluated to assess if the study will be set up nationwide (in the Netherlands).

Study objective

To evaluate the incidence, causes and characteristics of meningitis and/or encephalitis in patients of all ages:

1. To determine the causes of meningitis and/or encephalitis in children and adults

2. To evaluate the clinical signs and symptoms and CSF (and other material) laboratory characteristics of children and adults with a diagnosis of meningitis and/or encephalitis

3. To determine what materials (CSF, blood, faeces/rectal swab, nasopharyngeal aspirate/swab or throat swab) are most suitable for the detection of meningitis/encephalitis in children and adults.

4. To determine the impact of meningitis and/or encephalitis on the health care systems in terms of costs, antibiotic use, morbidity and mortality.

Study design

This is a prospective observational study. A pilot (duration 1 year) will be initiated in 3 regional hospitals in Amsterdam and Almere, the Netherlands. If this pilot is successfull, the study will be extended to the whole country.

Study burden and risks

The burden consists of the collection of one bloodsample, one throatswab or nasopharyngeal aspirate and one faecessample or rectal swab. The extent of this burden is estimated as low. As far as we know, there are no risks of the above mentioned collection of materials.

Contacts

Public Academisch Medisch Centrum

Meibergdreef 9 1100 DD Amsterdam NL **Scientific** Academisch Medisch Centrum

Meibergdreef 9 1100 DD Amsterdam NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years) Adolescents (16-17 years) Adults (18-64 years) Children (2-11 years) Elderly (65 years and older)

Inclusion criteria

Patients of all ages (including premature born infants) with a clinical suspicion of meningitis or encephalitis of whom central spine fluid is obtained, are eligible for inclusion in this study.

Exclusion criteria

- neurosurgical operation in recent past (last 3 months)

- drain with connection to cerebrospinal fluid

4 - Paediatric and Adult Causes of Encephalitis and Meningitis: The PACEM study. 25-05-2025

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):	16-01-2012
Enrollment:	200
Туре:	Actual

Ethics review

Approved WMO	
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

ССМО

ID NL36747.018.11