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Multi-centre European study of major infectious disease syndromes - Arboviral compatible febrile illness

Submission date
11/08/2015

Recruitment status
No longer recruiting

Registration date
21/01/2016

Overall study status
Completed

Last Edited
05/12/2018

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Arboviruses are a group of viruses that can be transmitted to humans by insects and ticks. Arbovirus infections usually only cause mild disease, but some people they can be more serious and can lead to admission to hospital. The symptoms of an arbovirus infection can resemble other illnesses, and so very specific testing is needed for it to be diagnosed. The symptoms can also vary a lot between people, which makes diagnosis even more difficult. Little is known about how many people are affected by these viruses in Europe, or why some people develop more severe symptoms. The aim of this study is to find out how many people who are admitted to hospital with similar symptoms actually do have an arbovirus infection.

Who can participate?
Adults admitted to hospital with suspected arbovirus infection.

What does the study involve?
Participants have blood samples (and spinal fluid samples if available) collected when they are admitted to hospital, on day 7 (or when they are discharged from hospital if before 7 days), day 28, and on day 60. These samples are then tested in the laboratory for the presence of antibodies against arboviral infections. Participants also complete a number of questionnaires on day 28 and day 60 in order to assess their recovery and state of health.

What are the possible benefits and risks of participating?
There are no direct benefits to taking part in this study. There is no risk in taking part other than some possible discomfort when the blood samples are collected.

Where is the study run from?
1. Infectious and Tropical Diseases Hospital (Romania)
2. Clinic for Infectious Diseases (Croatia)
3. Ippokrateio General Hospital of Athens (Greece)

4. University Hospital Centre "Mother Teresa" (Albania)
5. University Clinical Center of Kosovo (Kosovo)
6. Clinical Center of Serbia (Serbia)

When is the study starting and how long is it expected to run for?
May 2016 to December 2017

Who is funding the study?
European Commission (Belgium)

Who is the main contact?
Ms Emmanuelle Denis

Study website
http://www.prepare-europe.eu/About-us/Workpackages/Workpackage-3

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Multi-centre EuRopean study of MAjor Infectious Disease Syndromes (MERMAIDS) – Observational Study of Arboviral Compatible Febrile Illness in Hospitalised Patients

Acronym
MERMAIDS-ARBO

Study objectives
The aim of this study is to estimate the proportion of adult hospital admissions with a febrile illness in South East Europe that are attributable to four arbovirus infections:
1. West Nile Virus (WNV)
2. Toscana virus (TOSV)
3. Tick borne encephalitis virus (TBEV)
4. Crimean Congo haemorrhagic fever virus (CCHFV)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxford Tropical Research Ethics Committee (OxTREC), 12/08/2015, ref: 31-15

Study design
Multi-centre observational case series study

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Arboviral compatible febrile illness

Interventions
Blood and, if available, spinal fluid samples will be collected at baseline, day 7 (or date of hospital discharge), day 28 and day 60. Samples will be analysed to identify causative pathogens and to measure antibody levels.

Intervention Type
Other

Primary outcome measure
Proportion of adults hospitalised with a clinically compatible illness who have laboratory confirmed or probable TBEV, WNV, TOSV or CCHFV infection is determined at day 60.

Secondary outcome measures
1. Proportion of patients treated with antivirals, antibiotics and/or steroids
2. Daily clinical observations (vital signs, neurological and haemorrhagic symptoms) during admission
3. Level of consciousness determined according to the Glasgow Coma Scale in Adults at baseline
4. Proportion of patients receiving intensive care treatment and duration
5. Antibody levels are measured from blood samples at baseline, 7, 28 and 60 days
6. Neurological recovery and health outcomes are measured using the modified Rankin scale, Liverpool outcome scores for adults and EQ-5D-5L assessment at discharge and follow up (day 28 and 60)
7. Mortality rate is determined at day 60

Overall study start date
01/05/2016

Completion date
05/01/2020

Eligibility

Key inclusion criteria
1. Adults (≥ 18 years old) admitted to hospital from 1st May – 31st October inclusive with recent onset (<21 days) of symptoms of suspected Encephalitis or Meningitis .

OR

2. Rapid onset of temp.≥ 38˚C of unknown etiology (<21 days) AND at least ONE of the signs or symptoms below:
2.1. A neurological symptom (such as: neck stiffness, photophobia, partial paralysis, polyradiculitis, periorbital pain, confusion, altered mental state)
2.2. Severe headache
2.3. Myalgia
2.4. Backache
2.5. Arthralgia
2.6. Maculopapular rash

2.7. Haemorrhagic symptom
2.8. Thrombocytopenia (<150 000 cells per microliter of blood)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1500

Key exclusion criteria
1. Patients with non-infectious central nervous system (CNS) disorders due to hypoxic, vascular, toxic or metabolic causes
2. Patients where the symptoms are due to another confirmed cause, such as bacterial infection, malaria, malignancy, immune disorders, trauma
3. Patients with a focal source of infection identified, such as pneumonia, viral respiratory tract infection, acute infectious diarrhea, urinary tract infection (positive urine cultures), or skin or soft-tissue infection
4. Patients where the symptoms are caused by recurrence of a pre-existing condition

Date of first enrolment
01/05/2016

Date of final enrolment
31/10/2019

Locations

Countries of recruitment
Albania

Croatia

Greece

Kosovo

Romania

Serbia

Study participating centre
Infectious and Tropical Diseases Hospital
Sos. Mihai Bravu nr. 281
Sector 3
Bucuresti
Romania
030303

Study participating centre
Klinika za infektivne bolesti (Clinic for Infectious Diseases)
Mirogojska 8
Zagreb
Croatia
10 000

Study participating centre
Ippokrateio General Hospital of Athens
Sofias 114
Athens
Greece
115 27

Study participating centre
Qendra Spitalore Universitare “Nënë Tereza” Tirane (University Hospital Centre "Mother Teresa")
Rruga e Dibrës 372
Tirana
Albania
1000

Study participating centre
University Clinical Center of Kosovo
Prishtina
Kosovo
10000

Study participating centre
Clinical Center of Serbia
Pasterova 2
Belgrade
Serbia
11000

Sponsor information

Organisation
University of Oxford

Sponsor details
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Headington
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United Kingdom
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ctrg@admin.ox.ac.uk

Sponsor type
University/education

Website
http://www.admin.ox.ac.uk/researchsupport/ctrg/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
European Commission

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκής Επιτροπής, Европейската комисия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságról, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
The results will be reported in the annual reports for the sponsors, ethics commission and funders. The final results will be reported in a final report sent to all of the above. Results will also be published on the PREPARE website and in open-access, peer-reviewed publications and at scientific meetings and conferences.

Intention to publish date
01/06/2020

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository