MOBI-KIDS; Study on communication technology, environment and brain tumours in young people.

Published: 16-03-2011
Last updated: 04-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Observational non invasive

Summary

ID

NL-OMON39720

Source
ToetsingOnline

Brief title
MOBI-KIDS

Condition

- Nervous system neoplasms malignant and unspecified NEC
- Nervous system neoplasms benign

Synonym
brain tumor, intracranial neoplasm

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Europese Unie;ODAS Stichting

Intervention

Keyword: brain tumours, environment, mobile phone, young people

Outcome measures

Primary outcome

Primary brain tumor (glioma, choroid plexus tumors, neuronal and mixed neuronal-glial tumors, other neuroepithelial tumors, tumors of the pineal region, embryonal tumors, tumors of cranial and paraspinal nerves, tumors of the meninges, tumors of meningothelial cells, other neoplasms of the meninges, tumors of the sellar region).

Secondary outcome

Not applicable.

Study description

Background summary

Mobile phone use has increased dramatically in many countries since its introduction in the early-to-mid 1980s. This technology has brought with it some concerns about health and safety. In the late 1990s, several expert groups critically reviewed the evidence on health effects of low-level exposure to radiofrequency (RF) and extremely low frequency (ELF) electromagnetic fields and recommended research into the possible adverse health effects of mobile telephony. As a result, in 2000 a multinational epidemiological case-control study, INTERPHONE, was conducted in 13 countries to investigate whether mobile phone use increases the risk of cancer and more specifically, whether RF fields emitted by mobile phones are carcinogenic. The results did not provide a clear picture and room is left for a possible increased risk of brain tumors among people who used a mobile telephone for more than 10 years.

The INTERPHONE study focused on adults (30-59 years old) and has no information on risks from exposure in childhood, as mobile phone use in children at the time the study started was still low. The rapid worldwide increase in mobile phone use in adolescents and, more recently, children, has generated considerable interest in the possible health effects of exposure to RF fields.

Concern originates from the fact that, if there is a risk, it is likely to be greater for use at these ages for the following reasons: the developing neurological system may be more sensitive to the effects of RF; the spatial distribution of RF energy absorption in the brain of children and adolescents may be different than that in adults; and because they start mobile phone use at an early age, and (at least for adolescents) tend to use phones more than adults, children and adolescents are likely to have greater lifetime cumulative exposures to RF from mobile phones than those who started using the phones in adulthood.

Because of these concerns, a number of national and international bodies have recommended studies of exposure in childhood and adolescents as one of the high priority areas for RF research. These include the International EMF Project, the research agenda put forward by the EU-funded EMF-NET Coordination Action, and the US National Research Council 2008 report. In addition, a number of national EMF research programs have defined this topic as a priority.

Study objective

The overall objective of the MOBI-KIDS study is to assess the potential carcinogenic effects of childhood and adolescent exposure to RF and ELF from mobile telephones on the central nervous system (CNS).

In order to achieve the overall objective, the operational objectives are the following:
• To conduct a multinational epidemiological case-control study of brain tumors in young people in 9 countries under the EU grant, and in 4 non-European countries which are not funded by the EU grant.
• To develop and validate improved indices of RF and ELF exposure, and assess related uncertainties, for all of the subjects in the study.
• To analyze the relation between risk of brain tumors and exposures to RF and ELF from mobile phones and other relevant and important sources of exposure in the general environment of young people.

Study design

This study is designed as a prospective multinational case-control study of brain tumors in young people. The exposure to RF and ELF from mobile telephones and other relevant sources in the environment will be estimated based on an interview with the study participants.

Study burden and risks

The burden of participation will be minimal and consists of an interview of about one hour with the study participants (and their parents/guardians) and the collection of a saliva sample. There are no risks associated with

participation nor any benefits.

Contacts

Public
Universiteit Utrecht

Jenalaan 18d
Utrecht 3584 CK
NL
Scientific
Universiteit Utrecht

Jenalaan 18d
Utrecht 3584 CK
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

Cases: Boys and girls aged 10-24 years with a confirmed diagnosis of a primary brain tumor (benign or malignant), diagnosed during the study period in one of the participating Dutch hospitals.
Controls: Boys and girls aged 10-24 years hospitalized for acute appendicitis during the study period in one of the participating Dutch hospitals. Controls will be individually matched to cases on age, sex and medical district.

Exclusion criteria

Cases: insufficient knowledge of the Dutch language.
Controls: insufficient knowledge of the Dutch language; mental disability; history of a brain tumor.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-07-2011
Enrollment:	315
Type:	Actual

Ethics review

Approved WMO Date:	16-03-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-02-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	15-03-2012

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-11-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	09-01-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-12-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	11-09-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL31691.041.10