The effect of mobile phone use on symptoms and neuroendocrine function in 'normal' and 'hypersensitive' users

Submission date Recruitment status Prospectively registered 21/12/2005 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 10/01/2006 Completed [X] Results [] Individual participant data Last Edited Condition category 09/10/2008 Mental and Behavioural Disorders

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives

Exposure to pulsed 900 MHz Global System for Mobile Communications (GSM) radiofrequency fields will be associated with higher symptom reporting and altered neuroendocrine function in comparison to exposure to unpulsed radiofrequency fields or a 'sham' condition.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study has been approved by the Institute of Psychiatry/South London and Maudsley NHS Trust Ethical Committee (Research)(reference: 131/02)

Study design

Double-blind, within participants, randomised controlled trial

Primary study design

Observational

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

Health condition(s) or problem(s) studied

Sensitivity to radiofrequency fields / electrosensitivity

Interventions

Each participant will be exposed to each of three conditions: pulsed 900 MHz GSM radiofrequency fields, unpulsed radiofrequency fields of the same mean power, and a sham (placebo) condition. Each of these conditions will last for 50 minutes. The order these conditions will be presented in for each participant will be determined using block randomisation.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Our primary outcome will consist of self-reported headache severity during exposure, recorded using a 0-100 mm visual analogue scale.

Secondary outcome measures

Secondary outcomes will include: self-reported severity for nausea, fatigue, dizziness, skin itching, tingling or stinging, sensations of warmth or burning on skin, and eye pain or dryness.

Neuroendocrine outcomes will include: plasma levels of cortisol, adrenocorticotropic hormone, growth hormone and prolactin.

Secondary outcomes will be recorded during each of the three experimental provocations.

Overall study start date

01/09/2003

Completion date

30/06/2005

Eligibility

Key inclusion criteria

Two samples will be tested, consisting of 'control' and 'sensitive' participants. To be eligible for the sensitive group, participants must report experiencing often headaches within 20 min of using a GSM mobile phone. Only participants who do not attribute any symptoms to mobile phone signals will be eligible for inclusion in the control group.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

60 participants will be recruited for each group

Key exclusion criteria

Participants will be excluded if: under 18, over 75, pregnant, suffering from a psychotic illness, currently using antidepressants, or if they report severe symptoms at baseline while in the testing room.

Date of first enrolment

01/09/2003

Date of final enrolment

30/06/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Mobile Phone Research Unit London United Kingdom SE5 9PJ

Sponsor information

Organisation

Mobile Telecommunications and Health Research programme (UK)

Sponsor details

MTHR, c/o HPA Centre for Radiation Protection Chilton Didcot Oxfordshire United Kingdom OX11 0RQ mthr@nrpb.org

Sponsor type

Other

Website

http://www.mthr.org.uk

Funder(s)

Funder type

Not defined

Funder Name

Funded by the UK Mobile Telecommunications and Health Research programme (MTHR)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient- facing?
Results article	Results	06/03 /2006		Yes	No
Other publications	Within participants double blind randomised provocation study:	15/04 /2006		Yes	No