Evaluation of a Specialized Therapeutic Care of Patients Presenting an Intolerance Attributed to Electromagnetic Fields (IEI-CEM)

This study is currently recruiting participants.

Verified May 2013 by *Assistance Publique - Hôpitaux de Paris*

Sponsor:
Assistance Publique - Hôpitaux de Paris

Collaborators:
ANSES, France
INERI, Verneuil-En-Halatte, France

Information provided by (Responsible Party):
Assistance Publique - Hôpitaux de Paris

ClinicalTrials.gov Identifier:
NCT01854801

First received: April 24, 2013
Last updated: May 13, 2013
Last verified: May 2013
History of Changes

Purpose

The purpose of the study is to evaluate efficacy of a 14 months follow-up and individual medical care of electro-sensitive patients: by measurement of health status, sensitivity to electromagnetic fields exposures, and quality of life.

Condition	Intervention
Idiopathic Environmental Intolerance Attributed to Electromagnetic Fields	Other: Individual medical Care Other: Individual electromagnetic exposures

Study Type: Interventional
Study Design: Endpoint Classification: Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Evaluation of a Specialized Therapeutic Care of Patients Presenting an Idiopathic Environmental Intolerance Attributed to Electromagnetic Fields

Resource links provided by NLM:

MedlinePlus related topics: Electromagnetic Fields

U.S. FDA Resources

Further study details as provided by Assistance Publique - Hôpitaux de Paris:

Primary Outcome Measures:

- Measurement of symptoms severity [Time Frame: At 1 month after inclusion and at 12 months.] [Designated as safety issue: No]

  At month 1 and at 12 months the severity of symptoms is evaluated by a self-questionary filled in during 7 days. The level of severity of each symptom occurring during a week, will be self-evaluated by the patient on the base of a 0 to 5 scale. Following the intervention we expect a reduction in the severity of symptoms described.

- Measurment of symptoms frequency [Time Frame: At 1 month after inclusion and at 12 months.] [Designated as safety issue: No]

  At month 1 and at 12 months the symptoms frequency is evaluated by a self-questionary filled in during 7 days. Each symptom occurring during a week is reported by the patient allowing calculation of a frequency in symptoms appearance. Following the intervention we expect a reduction in the frequency of symptoms described.

- Sensitivity to electromagnetic fields [Time Frame: Visit 1 (day 0)/Visit 3 (14 months)] [Designated as safety issue: No]

  At visit 1 (day 0) and visit 3 (14 months) the EMF sensitivity is evaluated by the self-questionary.

Secondary Outcome Measures:

- Quality of life evaluation [Time Frame: At visit1 (day 0) and visit 3 (14 months) .] [Designated as safety issue: No]

  At visit1 (day 0) and visit 3 (14 months) the quality of life is evaluated by the self-questionary (SF-36)

- Compliance to the study design [Time Frame: At each Visit (Day 0, Month 1, Month 6 and month 14)] [Designated as safety issue: No]

Estimated Enrollment:	110
Study Start Date:	March 2012
Estimated Study Completion Date:	December 2015
Estimated Primary Completion Date:	May 2015 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Experimental Patients who declare themselves to be intolerant to electromagnetic fields benefit from medical care in occupational and environmental diseases centers and from a measurement of individual electromagnetic exposures and symptoms episodes. Each patient is his own control.	Other: Individual medical Care Individual medical care in occupational and environmental diseases centers Other: Individual electromagnetic exposures During 7 days, patient hold a dosimeter measuring their electromagnetic exposures for FM, TV, GSM, DECT, WIFI, TETRA and relay antenna emissions. During this week, patients notify intensity and time of their symptoms on a self-questionary

Detailed Description:

110 patients suffering from Idiopathic Environmental Intolerance attributed to electromagnetic fields (IEI-EMF) are expected in this trial.

Type of trial: Interventional multicenter study, non-randomized, with measurement before and after intervention. Each patient is his own control.

Primary outcome: Efficacy of an individual medical care on electro sensitive (IEI CEM) patients evaluated from the improvement of health status, sensitivity to electromagnetic fields (EMF) exposure, and quality of life.

Scheme:

Visit 1(T0): Patients undergo a specialized medical examination: a standardized medical record is filled in. Physicians evaluate the psychological impact of IEI-EMF and a psychotherapeutic care is proposed if necessary. Patients fill in 2 self-questionaries: quality of life (SF-36) and EMF exposure sensitivity.

After the visit 1, a symptoms self-administrated questionary n°1 is completed during 7 days.

1 month after inclusions (T1), radiofrequencies (RF) are recorded by a dosimeter worn by patients for 7 days; patient fill-in the symptoms self-administrated questionary n° 2 during the same time.

Visit 2: 6 months after inclusion, analysis of symptoms and RF exposure is restituted at patient. An adapted care is proposed.

12 months after inclusion (T12), patients complete the symptoms self-administrated questionary n°3.

Visit 3: 14 months after inclusion (T14), patients have medical examination and complete the quality of life and EMF exposure sensitivity self-questionaries. Standardized medical record is filled in by physicians. Patient and physician discuss the global and comparative analysis of individual results.

Inclusion duration: 24 month; Follow-up: 14 months; Study duration: 38 months.

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Subjects who declare themselves to be intolerant to electromagnetic fields
- Subjects over 18 years old
- Subjects affiliated to a social security scheme
- Subjects who signed the consent form

Exclusion Criteria:

- Subject with a disorder of the understanding of the French language at the discretion of the investigator
- Pregnant women,
- Persons deprived of their liberty, persons under guardianship, and persons in emergency situations.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01854801

Contacts

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Locations

France

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Sponsors and Collaborators

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Investigators

Study Director: Lynda BENSEFA-COLAS, MD Service de Pathologie Professionnelle, Hopital Cochin, AP-HP, Paris

Study Director: Rene de SEZE, MD INERIS (Institut National de l'EnviRonnement Industriel et des RisqueS)

More Information

Additional Information:

The link presents the recruiting centers

No publications provided

Responsible Party:	Assistance Publique - Hôpitaux de Paris
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Other Study ID Numbers:	P100120
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Health Authority:	France: Ministry of Health

Keywords provided by Assistance Publique - Hôpitaux de Paris:

IEI-EMF
WI-FI
DECT
Electro-sensitivity
Radiofrequency
EHS
Idiopathic
Environmental
Intolerance fields
Mobile phone

Additional relevant MeSH terms:
Multiple Chemical Sensitivity
Environmental Illness
Hypersensitivity
Immune System Diseases

ClinicalTrials.gov processed this record on May 27, 2013

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