

Magnetic brain stimulation to improve fatigue, cognitive problems and nerve pain in people with toxic oil syndrome

Submission date 30/10/2026	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 30/10/2026	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 30/10/2026	Condition category Injury, Occupational Diseases, Poisoning	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Toxic oil syndrome is a long-term condition that affected people exposed during the toxic oil epidemic in Spain in 1981. Many people living with the condition still experience severe tiredness, problems with memory and thinking, nerve pain, and a reduced quality of life. This study aimed to find out whether a treatment called repetitive transcranial magnetic stimulation (rTMS), which uses magnetic pulses to stimulate specific areas of the brain, could help reduce fatigue and improve other symptoms. Researchers also looked at whether the treatment affected attention, thinking skills, nerve pain, and quality of life.

Who can participate?

Adults aged 18 to 80 years with clinically confirmed toxic oil syndrome could take part. Participants needed to have ongoing symptoms related to the condition, be medically stable, be able to understand the study information and give written consent, and be willing to attend treatment sessions and follow-up assessments.

What does the study involve?

Participants received repetitive transcranial magnetic stimulation (rTMS) treatment targeted at a region of the brain involved in attention, thinking, mood, and pain processing. The treatment consisted of 15 sessions over three weeks, with five sessions each week.

Participants attended assessments before treatment started, immediately after treatment finished, and again about 1 month, 6 months, and 12 months later. During these assessments, researchers measured fatigue, thinking and memory skills, pain, mood, anxiety, sleep quality, general health, and quality of life using questionnaires and cognitive tests.

What are the possible benefits and risks of participating?

Participants may have experienced improvements in fatigue, cognitive symptoms, nerve pain, or quality of life. However, as this was a research study, there was no guarantee that participants would benefit.

The treatment was non-invasive, meaning that it did not involve surgery. People with certain conditions that could increase the risk of side effects, such as epilepsy, uncontrolled seizures,

some brain disorders, or metal or electronic implants in the head or neck, could not take part. People who were unable to tolerate the rTMS procedure were also excluded from the study.

Where is the study run from?

The study was run from Hospital Universitario 12 de Octubre in Madrid, Spain. Recruitment took place in Spain.

When is the study starting and how long is it expected to run for?

November 2025 to September 2026.

Who is funding the study?

The study was investigator initiated and funded. The sponsor was Fundación de Investigación Biomédica Hospital Universitario 12 de Octubre.

Who is the main contact?

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Contact information

Type(s)

Scientific, Principal investigator, Public

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Additional identifiers

Study information

Scientific Title

Effects of repetitive transcranial magnetic stimulation on fatigue, cognitive impairment and neuropathic pain in adults with toxic oil syndrome: an open-label single-arm pilot study

Study objectives

The primary objective was to evaluate the efficacy of repetitive transcranial magnetic stimulation (rTMS) in reducing chronic fatigue in patients with toxic oil syndrome. Secondary objectives were to assess changes in attention and executive functions, neuropathic pain, and quality of life following treatment.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 21/10/2025, Dictamen del Comité de Ética de Investigación con Medicamentos para Investigación Clínica con Productos Sanitarios del Instituto de Investigación Hospital 12 de Octubre (Comité de Ética de Investigación, Hospital 12 de Octubre, Av. de Córdoba s / n, Madrid, 28041, Spain; +34 913908000; ceic@h12o.es), ref: N° CEIm: 25/646

Primary study design

Interventional

Allocation

N/A: single arm study

Masking

Open (masking not used)

Control

Uncontrolled

Assignment

Single

Purpose

Treatment

Study type(s)**Health condition(s) or problem(s) studied**

Toxic oil syndrome

Interventions

Participants received high-frequency repetitive transcranial magnetic stimulation (rTMS) applied to the left dorsolateral prefrontal cortex. The approved protocol specified 15 treatment sessions delivered over three consecutive weeks, with five sessions per week. Stimulation was delivered at 10 Hz and 100% of the individual motor threshold, with approximately 1,500 pulses per session, using 4-second stimulation trains separated by 26-second inter-train intervals. Motor threshold was determined individually using single-pulse stimulation over the cortical motor hotspot. Treatment was administered in an outpatient clinical setting by personnel trained in non-invasive neuromodulation. Clinical assessments were planned at baseline, immediately after treatment, and during follow-up at approximately 1, 6 and 12 months.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

M100 Ultimate repetitive transcranial magnetic stimulation (rTMS) system — Shenzhen Yingchi Technology Co., Ltd.

Primary outcome(s)

1. Fatigue-related interference with daily functioning measured using Fatigue Impact Scale for Daily Use (D-FIS), Spanish version; higher scores indicate greater fatigue-related interference with daily functioning at baseline, immediately after completion of the rTMS treatment course, and follow-up at approximately 1, 6 and 12 months

Key secondary outcome(s)

Completion date

01/09/2026

Eligibility

Key inclusion criteria

1. Adults aged 18–80 years
2. Clinically confirmed toxic oil syndrome based on documented or probable exposure and compatible clinical manifestations
3. Persistent clinical manifestations attributable to toxic oil syndrome, including neurological and /or cognitive symptoms
4. Clinically stable at enrolment, without an acute or decompensated medical condition
5. Able to understand the study information and provide written informed consent
6. Able and willing to attend the stimulation sessions and scheduled clinical assessments

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

80 Years

Sex

All

Total final enrolment

17

Key exclusion criteria

1. Metallic or electronic implants in the head or neck incompatible with rTMS
2. Active epilepsy or uncontrolled seizures
3. Active brain tumour or significant structural brain disease
4. Known or suspected pregnancy
5. Severe or unstable psychiatric disorder

- 6. Active substance misuse
- 7. Medication or other clinical conditions considered to substantially increase seizure risk
- 8. Inability to tolerate the rTMS procedure

Date of first enrolment

25/11/2025

Date of final enrolment

09/06/2026

Locations

Countries of recruitment

Spain

Sponsor information

Organisation

Fundación de Investigación Biomédica Hospital Universitario 12 de Octubre

Funder(s)

Funder type**Funder Name**

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2	01/10/2025	30/10/2026	No	No