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Topiramate in skin picking disorder

Submission date
14/12/2016

Recruitment status
No longer recruiting

Registration date
23/12/2016

Overall study status
Completed

Last Edited
30/01/2017

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Skin picking disorder is a mental health condition characterized by the repetitive picking of the skin until damage is caused. It is considered to be an impulse control problem, where a patient cannot control the compulsion to pick their skin, similar to obsessive compulsive disorder (OCD). Skin picking disorder can be extremely distressing for sufferers, as the damage the condition causes to the skin can be difficult to hide and prevent them from carrying out everyday activities. Topiramate is a type of medication called an anticonvulsant, which is usually used for treating seizures. The aim of this study is to find out whether topiramate is an effective treatment for skin picking disorder.

Who can participate?
Adults who suffer from skin picking which causes significant distress.

What does the study involve?
All participants are given 25mg topiramate to take once a day for a week so that any side effects can be noted. If they do not experience any side effects, the dose is then gradually increased to 100mg twice a day. Participants in both groups are followed up every two weeks for a total of 12 weeks to see if taking the medication has reduced their skin picking, as well as to assess their general mental wellbeing.

What are the possible benefits and risks of participating?
Participants may benefit from a reduction in skin picking. Some participants mood changes, however this will be closely monitored and the doses used tightly controlled.

Where is the study run from?
Jafferany Psychiatric Services (USA)

When is the study starting and how long is it expected to run for?
June 2012 to December 2018

Who is funding the study?
Jafferany Psychiatric Services (USA)

Who is the main contact?
Dr Mohammad Jafferany
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Jaffpsych001

Study information

Scientific Title
A pilot study of the use of topiramate in skin picking disorder

Study objectives
The aim of this study is to evaluate the efficacy of topiramate in skin picking disorder.

Null hypothesis:
There is no difference in skin picking after use of topiramate.

Experimental hypothesis:
There is a difference in skin picking after use of topiramate.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethics Committee of the Jafferany Psychiatric Services, 08/12/2013, ref: JP2013-001

Study design
Open-label flexible-dose trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Skin picking disorder

Interventions
Patients with skin picking will be enrolled in the study based upon diagnostic criteria by DSM 5 and followed for a 12-week period in an open label method. Patients will be started on 25mg topiramate once a day for during the first week. Monitoring of side effects will be done during this first week and if a patient tolerated the medication, the dose of topiramate will be increased to 25mg twice a day during the second week. Next month the dose will be increased to 50mg twice a day and third month 100mg twice a day. If the desired effect was obtained at a lower dose, such dose will be maintained. They will be seen weekly for two weeks and every two weeks for the remainder of the 12 weeks open label study. Adjusting the dose of their topiramate as clinically indicated will be the main intervention that patients are exposed to.

Patients will be followed up at 2 weeks, 4 weeks, 6 weeks, 8 weeks and 12 weeks. Primary outcome measure that will be assessed include the mean time spent picking per day as each participant will be asked to keep a diary of time spent picking each day. Secondary outcomes will be evaluated using SPS-Y-BCOS, skin picking scale, Beck anxiety inventory, Beck depression inventory, CGI-severity and CGI-improvement.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Topiramate

Primary outcome measure

Mean time spent picking per day, measured using participant diaries at 2, 4, 6, 8 and 12 weeks

Secondary outcome measures
1. Skin picking, obsessions and compulsions are measured using SPS-Y-BCOS at 2, 4, 6, 8 and 12 weeks
2. Skin picking frequency is measured using the skin picking scale at 2, 4, 6, 8 and 12 weeks
3. Anxiety is measured using the Beck anxiety inventory at 2, 4, 6, 8 and 12 weeks
4. Depression is measured using the Beck depression inventory at 2, 4, 6, 8 and 12 weeks
5. Severity is measured using the CGI-severity at 2, 4, 6, 8 and 12 weeks
6. Improvement in clinical condition is measured using the CGI-improvement at 2, 4, 6, 8 and 12 weeks

Overall study start date
01/06/2012

Completion date
29/12/2018

Eligibility

Key inclusion criteria
1. Recurrent skin picking resulting in skin lesions
2. Repeated attempts to decrease or stop skin picking
3. The skin picking causes clinically significant distress or impairment in social, occupational, or other important areas of functioning
4. The skin picking is not attributable to the physiological effects of a substance/another medical condition
5. The skin picking is not better explained by symptoms of another mental disorder
6. Age 18-60 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
20

Key exclusion criteria

1. Chronic unstable medical illness
2. Pregnancy or lactation
3. Being on other psychotropic medications
4. Current substance abuse
5. Psychotherapy in the last six weeks prior to commencing the study

Date of first enrolment
01/12/2013

Date of final enrolment
01/12/2017

Locations

Countries of recruitment
Pakistan

United States of America

Study participating centre
Jafferany Psychiatric Services
3215 Hallmark Ct
Saginaw
United States of America
48603

Sponsor information

Organisation
Jafferany Psychiatric Services

Sponsor details
3215 Hallmark Court
Saginaw
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Jafferany Psychiatric Services

Results and Publications

Publication and dissemination plan
Results to be published at a later date in a medical journal within three years of study commencement while final publication is anticipated two years after final study completion.

Intention to publish date
29/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mohammad Jafferany MD (jaffe1m@cmich.edu)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/01/2017		Yes	No