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A new combined treatment for post-concussion syndrome: a pilot trial

Submission date
15/03/2022

Recruitment status
No longer recruiting

Registration date
30/03/2022

Overall study status
Deferred

Last Edited
12/05/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
Post-concussion syndrome (PCS) is a complex disorder for which there is currently no cure. It is a collection of symptoms that some people develop after they have had a concussion. PCS can profoundly affect quality of life through symptoms such as pressure headache, migraine, dizziness, fatigue, sleep disturbances, blurred vision, and cognitive complaints such as forgetfulness and concentration difficulties. The complexity of PCS presents an ongoing challenge in clinical practice. Current approaches for treating PCS focus on the relief of individual symptoms. This study will investigate the effectiveness of a repurposed drug combination for PCS. This is a pilot trial, which means that it has been designed to provide initial evidence that will be used to inform a future larger trial.

Who can participate?
Patients aged 18 to 64 years with PCS

What does the study involve?
The study involves taking the combined drug intervention daily until PCS resolves or until the end of the 3-month maximum trial duration. There will be two clinic visits and a telephone appointment mid-trial and 2 months after the trial.

What are the possible benefits and risks of participating?
The overall benefit of taking part in this study is that the treatment may improve or resolve PCS. Participants will receive a copy of the overall trial results at the close of the study. As with all drug treatments, there is a risk of side effects. The side effects associated with the drugs used in this study have been reported to be minimal and the drugs are routinely prescribed by clinicians in the UK. Any suspected side effects are to be reported to the clinical lead straight away.

Where is the study run from?
The study is led by Durham University and the lead clinical site is Walkergate Park Centre for Neurorehabilitation and Neuropsychiatry in Newcastle upon Tyne (UK)

When is the study starting and how long is it expected to run for?
July 2021 to December 2025

Who is funding the study?
Northern Accelerator (UK)

Who is the main contact?
paul.chazot@durham.ac.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
1005607

Protocol serial number
1.0

Study information

Scientific Title
A new combined treatment for post-concussion syndrome: a pilot trial

Study objectives
An investigational neuroactive combination therapy for post-concussion syndrome (PCS) is effective for the treatment of post-concussion syndrome.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 23/12/2022, North West - Liverpool Central REC (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)207 104 8118; liverpoolcentral.rec@hra.nhs.uk), ref: 22/NW/0285

Primary study design
Interventional

Study design
Single-arm pilot intervention trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Post-concussion syndrome

Interventions
The treatment comprises two generic drugs in tablet form, to be taken with water, three times daily until PCS resolves or the end of the 3-month trial duration. All participants will receive the treatment intervention.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Investigational neuroactive combination therapy for PCS

Primary outcome(s)
The presence of post-concussion measured using the Rivermead Post Concussion Syndrome Questionnaire at baseline and week 12 or at full resolution of symptoms, whichever comes first

Key secondary outcome(s)
Pain and fatigue measured using the visual analogue scale at baseline and week 12 or at full resolution of symptoms, whichever comes first

Completion date
01/12/2025

Eligibility

Key inclusion criteria
1. PCS patients, aged 18 to 64 years. PCS is defined as the persistence of concussion symptoms, for more than 3 months after the initial concussion event
2. Current PCS confirmed by the presence of more than three symptoms on the Rivermead PCS

3. Not using any other pharmaceutical treatment for the management of PCS, e.g. antidepressants
4. Can provide signed informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
64 Years

Sex
All

Key exclusion criteria
1. Pregnancy
2. Breastfeeding
3. Hepatic insufficiency
4. Renal impairment
5. Any of the following BNF contraindications: acute porphyrias; epilepsy; Parkinson's disease; prostatic hypertrophy; pyloroduodenal obstruction; susceptibility to angle-closure glaucoma; urinary retention
6. Any of the following BNF contraindications: gastric ulcer; history of haemorrhagic stroke; increased risk of bleeding; recent or planned major surgery; underlying disorders of haemostasis; cerebral haemorrhage; Huntington's chorea

Date of first enrolment
16/05/2023

Date of final enrolment
01/03/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Walkergate Park Centre for Neurorehabilitation and Neuropsychiatry
Benfield Road
Newcastle upon Tyne
United Kingdom
NE6 4QD.

Sponsor information

Organisation
Durham University

ROR
https://ror.org/01v29qb04

Funder(s)

Funder type
University/education

Funder Name
Northern Accelerator

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date