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TB ShORRT UK: an observational study of new, shorter treatment regimens for drug-resistant tuberculosis in the UK

Submission date 20/12/2022	**Recruitment status** Recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 01/08/2023	**Overall study status** Ongoing	
Last Edited 31/07/2023	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
Until 2022 most people treated for drug-resistant TB in the world received treatment courses of 12-18 months with at least 5 toxic drugs including daily intra-muscular injections with a drug that carried a high risk of causing hearing loss.
Fortunately medical researchers have recently discovered new highly effective drug regimens which are shorter (6 months) and use therapies with fewer side effects (no deafness) not requiring injections.
TB ShORRT UK is designed to determine whether these new treatment regimens for drug-resistant TB will perform as well in the UK context, by recording and following closely the experiences of TB patients treated with them in the UK. The study protocol is derived from a World Health Organisation template and there are similar studies underway in more than a dozen other countries.

Who can participate?
Any patient of any age receiving TB treatment that is not the standard 'first-line' regimen will be eligible to take part - most participants will be people with drug-resistant TB but people unable to tolerate 'first-line' treatments will also be invited to join.

What does the study involve?
No additional tests or interventions will be required for the study. Data will be collected from the usual clinical visit schedule.

What are the possible benefits and risks of participating?
There are no risks to participation - treatment will be unchanged and there are no additional clinic visits or tests to those that would ordinarily be the 'standard of care' expected - the data (blood test results, weight, symptoms) will be recorded and analysed together with those of other patients.

Where is the study run from?
University College London Hospitals NHS Foundation Trust

When is the study starting and how long is it expected to run for?
February 2022 to February 2028

Who is funding the study?
The study team are applying for funding from NIHR (Research for Patient Benefit scheme)

Who is the main contact?
Prof Dave Moore, davidajmoore1@nhs.net

Contact information

Type(s)
Principal investigator

Contact name
Prof Dave Moore

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
317172

Protocol serial number
IRAS 317172

Study information

Scientific Title
TB ShORRT UK: an implementation evaluation of shorter, all-oral regimens for drug-resistant tuberculosis in the United Kingdom

Acronym
TB ShORRT UK

Study objectives
Novel, shorter regimens for treatment of MDRTB have been recommended by the WHO. In clinical trials these have been shown to be better tolerated and more efficacious than existing drug regimens. To accelerate adoption in countries, local demonstration of comparative performance, tolerability and acceptability to patients and healthcare staff is critical. This implementation research project, closely mirroring the parent template protocol developed by WHO/TDR, will gather the evidence required to determine if such regimens are well suited to the UK context and inform future policy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Tuberculosis resistant to first-line drug therapies or tuberculosis in patients intolerant of first-line drug therapies

Interventions
UK TB patients with drug-resistant TB or intolerant of first-line TB medications will receive regimens composed of second-line therapies as part of their standard of care. All such patients will be invited to participate in an observational cohort study to advance our understanding of the safety, tolerability and efficacy of new, shorter, all-oral treatment regimens which are being introduced worldwide, and presently in the UK. No additional tests or interventions will be required for the study. Standardised collection of data from usual clinical visit schedule will facilitate aggregate analyses.

Intervention Type
Mixed

Primary outcome(s)
1. Effectiveness, defined as the proportion of patients with a favourable outcome of "cured" or "treatment completed without clinical or bacteriologic evidence of failure" up to 12 months after the end of treatment
2. Safety, assessed as the proportion of patients experiencing a serious adverse event during treatment and up to 6 months after the end of treatment

Key secondary outcome(s))
1. Health-related quality of life, assessed using the EQ-5D-5L and FACIT-TB questionnaires at baseline, 4 months, end of treatment and 12 months after treatment completion

2. Stigma, assessed using the Modified Cataldo Lung Cancer Scale at baseline, 4 months, end of treatment and 12 months after treatment completion
3. Acceptability to healthcare workers, assessed using semi-structured interviews and framework analysis with two rounds of interviews 12-18 months apart
4. Cost-effectiveness of shorter all-oral regimens compared to longer course regimens, utilising a Markov model to assess the incremental cost incurred per QALY gained

Completion date
28/02/2028

Eligibility

Key inclusion criteria
UK TB patients receiving a treatment regimen other than first-line treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Key exclusion criteria
1. Patients unable or unwilling to provide informed consent

Date of first enrolment
01/11/2023

Date of final enrolment
28/02/2027

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Sponsor information

Organisation
University College London Hospitals NHS Foundation Trust

ROR
https://ror.org/042fqyp44

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded at present - funding application in process

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 later date

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