ISRCTN16699730 https://doi.org/10.1186/ISRCTN16699730

A clinical trial investigating the use of a drug called metformin as a way of reducing the cancer risk in people with Li Fraumeni Syndrome (LFS)

Submission date
27/10/2022

Recruitment status
Recruiting

Registration date
28/11/2022

Overall study status
Ongoing

Last Edited
09/12/2025

Condition category
Cancer

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

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-metformin-to-reduce-the-risk-of-cancer-in-people-with-li-fraumeni-syndrome-mili

Background and study aims
Metformin is a well-known and safe drug used to treat diabetes. Laboratory experiments have shown that, in mice with LFS, metformin can reduce the risk of them developing cancer. This is because metformin alters the metabolism of cells with mutated TP53 and makes them act more like normal cells. A small study was carried out in people with LFS which showed that metformin treatment caused the same kind of cellular changes that had been seen in the treated mice. However, this is not enough to conclude that metformin will reduce the risks of cancer in people with LFS. Further trials are needed with a larger participant population.

Who can participate?
This clinical trial is aimed at individuals 16 years or older with diagnosed Li Fraumeni Syndrome (LFS). LFS is a rare genetic condition that predisposes people to develop one or more cancers. It is caused by a mutation in a gene called TP53, either inherited from a parent or occurring as a new mutation at conception.TP53 is the most important anticancer gene in the body, its job is to stop cells becoming cancerous after they become damaged or stressed. For most people with cancer, the gene is only mutated in their cancer cells but, for people with LFS, it is mutated in all the cells in the body. This means there is a very high risk of developing cancer for people with LFS – a lifetime risk of 90% for women, and about 70% for men. Many people with LFS develop multiple cancers over their lifetimes. Cancers associated with LFS include rare bone and soft tissue sarcomas, childhood brain tumours and leukaemias, but also more common cancers such as breast cancer.

What does the study involve?
Half the people on the trial will take metformin every day for up to 5 years and the other half will not. This will be decided by a randomisation process whereby a computer will randomly

allocate each participant to either the intervention arm which is yearly surveillance and metformin or, to the control arm which is yearly surveillance alone and no metformin . All participants will have yearly visits to a select Investigator hospital. At the investigator hospital they will have check-ups for cancer which will include blood tests and also a whole-body MRI scan. The participants will have 6 monthly check-up phone calls with a designated research nurse team for the 5-year trial period.

What are the possible benefits and risks of participating?
Possible benefits:
Although there is little evidence that supports that metformin delays cancer in LFS, we do not know what the outcome will be and this is why we are conducting this trial. The information obtained from this trial will be used to support a future licencing decision for metformin as a cancer prevention agent for people with LFS.
All participants, even those who are not taking metformin, will have yearly MRI scans, physical examinations and blood tests to look for any signs of cancer.
The trial will help us understand how cancers form in LFS and how metformin affects this process. The trial will also help us understand the impact that having LFS has on quality of life.

Possible risks:
Metformin is widely used and is considered to be a safe drug with few side effects. We will be asking participants to provide more blood samples than they would normally do as some of these samples will be used for research purposes. Blood samples will be collected from a vein in the hand or arm of the participant and may cause bruising and/or fainting.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
January 2022 to December 2030

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).
George Pantziarka TP53 Trust (UK)
Cancer Research UK

Who is the main contact?
Lynda Swan, octo-mili@oncology.ox.ac.uk
Professor Sarah Blagden, sarah.blagden@oncology.ox.ac.uk

Contact information

Type(s)
Public

Contact name
Miss Imogen North

Contact details
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Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
2022-000165-41

Integrated Research Application System (IRAS)
1006131

ClinicalTrials.gov (NCT)
Nil known

Central Portfolio Management System (CPMS)
53679

National Institute for Health and Care Research (NIHR)
131239

Study information

Scientific Title
Metformin in Li Fraumeni Syndrome (MILI) Trial: A phase II randomised open-label cancer prevention trial of metformin in adults with Li Fraumeni Syndrome

Acronym

MILI

Study objectives
By altering the metabolism of the mutated cells, the anti-diabetic drug metformin will delay or inhibit cancer formation in people with a genetic diagnosis of Li Fraumeni Syndrome.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/09/2023, West of Scotland REC 1 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, United Kingdom; +44 (0)141 314 0212; WoSREC1@ggc.scot.nhs.uk), ref: 23/WS/0051

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Li Fraumeni Syndrome

Interventions
Current interventions, as of 08/04/2025:

This is a randomised clinical trial for participants with LFS as per the inclusion criteria below. People with LFS should undergone yearly MRI whole-body, breast and brain imaging but provision is erratic as not all hospitals are able to offer this service. The MILI trial will offer yearly whole-body (and brain) imaging at one of 5 investigator sites, as well as dermatological examination, haematological testing with blood samples also being collected for translational research in order to better understand the biology of LFS. Quality of Life questionnaires will assess the participants' well-being during the trial.
Metformin:
In addition to annual surveillance, half the participants will be randomised to receive daily metformin. Research in LFS mouse models has shown that metformin can delay the emergence of cancer. It is hoped that from data pooled from this trial and also similar international trials will provide enough evidence for metformin to be prescribed as a cancer preventative for people with LFS as well as advancing research into this condition.
The trial has a dose-titration phase which will assess the safety and toxicity of metformin to ensure the side-effect profile is consistent with that of the diabetic population. All participants randomised to metformin will begin with a daily starting dose of 500mg which will be increased at 2-weekly intervals over a period of 9 weeks until they are taking a daily dose of 2000mg, if tolerated. They will remain on this dose for the duration of the trial. From month 6 onwards, participants in both arms will be asked the same questions via telemed calls about the known metformin side-effects in order to assess the adverse-event rate in each arm. Participants in the

metformin arm will be asked questions about their adherence to taking metformin. The metformin tablets will be posted at intervals to the participants by the investigator (recruiting) hospital.

The LFS community have had input into the trial design. The group opted not to use a placebo but to have an open label design. Given that many participants would have to travel to a different hospital for imaging, the six-monthly assessments will conducted remotely via telemed calls by a central research nurse team based at the Oxford investigator site.

All participants will attend an initial visit for consent, screening and baseline at an investigator site. The following assessments will be carried out:
Screening Evaluations
• Written informed consent. If participant consent falls out of the allowed screening window for example due to a delay in imaging, the participant can be re-consented at the next opportunity and necessary screening assessments restarted.
• Evaluation against inclusion and exclusion criteria.
• Medical and surgical history to include cancer history, prior cancer therapies and procedures, and clinically significant disease,
• Concomitant diseases and medications
• Blood pressure
• Dermatological assessment (visual only). Any abnormalities identified at baseline should be recorded.
• Whole Body MRI to be conducted and reported within 28 days of consent (WB-MRIs conducted at the local supporting site will be accepted for baseline if they were done within 3 months prior to randomisation)
• Urine pregnancy test (women of childbearing potential, WOCBP) and who are sexually active.
• Fasting blood samples for baseline haematology, biochemistry, glucose, insulin, and IGF1.

Baseline evaluations
• Demographic details include age, sex, and self-reported race/ethnicity, childbirth status, family cancer history, educational background, geographical location, alcohol intake, smoking history.
• Body Mass Index: Height, weight and Body Mass Index (weight (in kg)/ height2 (in metres)=kg /m2)
• Blood samples for pharmacodynamic testing
• Quality of Life assessment using 12-item short form survey (SF12v2) & Cancer Worry Scale.
• Collect contact details: Name, postal address, phone number, email address

Randomisation
Randomisation should take place within 28 days of screening & baseline assessments .
Randomisation will be conducted by the investigator site using a computer program.
Participants will be allocated in a 1:1 ratio to metformin (investigational) or no metformin (control) arms:
-The investigational arm is metformin plus annual surveillance for 5 years. The starting dose of metformin is 500mg/day. It will be increased (if tolerated) at 2 weekly intervals to a total dose of 2000mg/day.
-The control arm is annual surveillance alone for 5 years.

Annual visits to investigator (recruiting) sites
Participants will undergo the following assessments at the annual visits to the Investigator sites (Month 12, M24, M36, M48, M60) – both arms
• Dermatological check up (visual only). Any abnormalities identified should be recorded
• Body Mass Index: Weight and Body Mass Index (weight (in kg (in metres)=kg/m^2)

• Fasting blood samples for haematology, biochemistry (vitamin B12 at year 5 only), and glucose, insulin and IGF1 levels (M12 only)
• Blood samples for pharmacodynamic testing
• Pregnancy check (WOCBP)
• WB & brain MRI (to be reported within 4 weeks of the scan) unless participant has had a Whole-Body & brain MRI in last 3 months
• Quality of Life assessment using 12-item short form survey (SF12v2), Cancer Worry Scale, Treatment Burden Questionnaire (TBQ) (if not already completed by participant electronically prior to the visit)

Dose Titration Phase – Metformin arm
D15, D29, D43 and D57
• Adverse event assessment: Record and grade (using NCI CTCAE criteria) of reportable adverse events with date of onset, event diagnosis (if known) or sign/symptom, severity, time course, duration and outcome. Grade 2 or above events to be shared with PI for review and causality assessment and reporting if they meet the criteria for an SAE.
• New concomitant medications: provide generic name where applicable, dose, frequency, route, start date and indication,
• Additional investigations: check if participant has undergone any additional medical investigations.
• Dose-titration decision: depending on the grade of the Adverse Reactions (ARs), participants will be advised to increase, continue on same dose, or reduce metformin dose.
• Contact details check (D57): check for any updates to participant contact details (for sending next batch of metformin)

Six-monthly telemed calls
Participants will be phoned six-monthly by a research nurse telemed team (Month 12, M18, M24, M30, M36, M42, M48, M54) – both arms
They will be asked about the following:
• New concomitant medications: provide generic name where applicable, dose, frequency, route, start date and indication
• Adverse event assessment: Record and grade (using NCI CTCAE criteria) of reportable adverse events with date of onset, event diagnosis (if known) or sign/symptom, severity, time course, duration and outcome and causality.
• Additional investigations: Check if participant has undergone any additional investigations
• Contact details check: check for any updates to participant contact details
• Pregnancy check (WOCBP) (M18, M30, M42, M54)
• Record dates and outcomes of SOC surveillance: Dates and results (where known) of breast scans
Metformin Arm Only:
• Pregnancy check for partners of participants
• Medication Adherence using 5-Item Medicine Adherence Rating Scale (MARS-5)

Follow-up:
There is no follow-up unless a participant has withdrawn early from the trial. For those who withdraw early, the investigator site will follow-up the participant's health status with the local clinical team annually, where possible, for up to 5 years or until the trial ends (whichever comes first)

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Previous interventions:

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The LFS community have had input into the trial design. The group opted not to use a placebo but to have an open label design. Given that many participants would have to travel to a different hospital for imaging, the six-monthly assessments will conducted remotely via telemed calls by a central research nurse team based at the Oxford investigator site.

All participants will attend an initial visit for consent, screening and baseline at an investigator site. The following assessments will be carried out:

Screening Evaluations

• Written informed consent. If participant consent falls out of the allowed screening window for example due to a delay in imaging, the participant can be re-consented at the next opportunity and necessary screening assessments restarted.
• Evaluation against inclusion and exclusion criteria.
• Medical and surgical history to include cancer history, prior cancer therapies and procedures, and clinically significant disease,
• Concomitant diseases and medications
• Physical Examination: Blood pressure, respiratory, cardiovascular, abdominal examination, lymph nodes, breast exam
• Dermatological assessment (visual only). Any abnormalities identified at baseline should be recorded.
• Whole Body MRI to be conducted and reported within 28 days of consent (WB-MRIs conducted at the local supporting site will be accepted for baseline if they were done within 3 months prior to randomisation)
• Brain scan: to be conducted if no previous brain scan.
• Urine pregnancy test (women of childbearing potential, WOCBP) and who are sexually active.
• Fasting blood samples for baseline haematology, biochemistry, glucose, insulin, and IGF1.

Baseline evaluations
• Demographic details include age, sex, and self-reported race/ethnicity, childbirth status, family cancer history, educational background, geographical location, alcohol intake, smoking history.
• Body Mass Index: Height, weight and Body Mass Index (weight (in kg)/ height2 (in metres)=kg /m2)
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-The control arm is annual surveillance alone for 5 years.

Annual visits to investigator (recruiting) sites
Participants will undergo the following assessments at the annual visits to the Investigator sites (Month 12, M24, M36, M48, M60) – both arms
• Physical and dermatological examination: Respiratory, cardiovascular, abdominal examination, lymph nodes, breast exam, dermatological assessment (visual only). Any abnormalities identified should be recorded.
• Body Mass Index: Weight and Body Mass Index (weight (in kg (in metres)=kg/m²)
• Fasting blood samples for haematology, biochemistry (vitamin B12 at year 5 only), and glucose, insulin and IGF1 levels (M12 only)
• Blood samples for pharmacodynamic testing
• Pregnancy check (WOCBP)
• WB & brain MRI (to be reported within 4 weeks of the scan) unless participant has had a Whole-Body & brain MRI in last 3 months
• Record dates and outcomes of SOC surveillance: Dates and results (where known) of breast scans
• Quality of Life assessment using 12-item short form survey (SF12v2), Cancer Worry Scale, Treatment Burden Questionnaire (TBQ) (if not already completed by participant electronically prior to the visit)

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• Additional investigations: Check if participant has undergone any additional investigations
• Contact details check: check for any updates to participant contact details
• Pregnancy check (WOCBP) (M18, M30, M42, M54)
Metformin Arm Only:
• Pregnancy check for partners of participants
• Medication Adherence using 5-Item Medicine Adherence Rating Scale (MARS-5)

Follow-up:
There is no follow-up unless a participant has withdrawn early from the trial. For those who withdraw early, a yearly telephone follow-up will be provided by the telemed team where possible for up to 5 years. Assessments will be conducted to:
• Ascertain health status/ Cancer diagnosis check

Intervention Type
Drug

Phase
Phase II

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

Primary outcome(s)
Cancer free survival – with "cancer" event defined as pathologically confirmed diagnosis of malignant cancer identified during trial participation or death from any cause up to 5 years (60 months) following randomisation

Key secondary outcome(s))
1. Tumour free survival – with a "tumour" event including pathologically confirmed diagnosis of malignant cancer or clinically/scan detected benign or premalignant lesion (e.g. ductal carcinoma in situ - DCIS) identified during trial participation or death from any cause. Measured by time to development of new cancer and/or benign lesion in each trial arm within 60 months of randomisation and % events.
2. Time from randomisation to death from any cause within 60 months post-group allocation and % events.
3. Number and type of emerging cancers, including size, stage and histological grade at diagnosis measured by number, type and stage of cancer diagnosed within each trial arm within 60 months post-group allocation
4. Relevant treatment-emergent adverse events and clinically significant laboratory changes (per NCI CTCAE v5.0) or changes in physical exam and/or vital signs in investigation arm compared to baseline measured by number of and severity of relevant AEs in metformin trial

arm within 60 months post-group allocation
5. MARS-5 questionnaire score in the metformin arm from group allocation to 60 months
6. Change in 12-item short form survey (SF12v2), Cancer Worry Scale, Treatment Burden Questionnaire (TBQ) over 60 months post-group allocation
7. Baseline weight, BMI and lifestyle factors (e.g. smoking and diet)

Completion date
31/12/2030

Eligibility

Key inclusion criteria
1. Diagnosis of LFS from confirmed pathogenic TP53 variant (class IV or V by CanVIG-UK criteria
2. Aged >16 years
3. Capable of understanding the consent process and participating in the study (including proving blood samples), in the investigators' decision

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current exclusion criteria as of 01/04/2025:

1. Currently taking metformin
2. Metformin intake for more than 3 months in total, within the 2 years antecedent to the date of trial enrolment
3. Completion of cancer systemic therapy within the 6 months antecedent to the date of trial enrolment
4. Current type 1 or 2 diabetes mellitus
5. Presence of active ongoing cancer /or currently receiving cancer treatment (excluding maintenance treatments e.g., hormones)
6. Current pregnancy or lactation

7. Gastro-intestinal condition (such as short-bowel syndrome) that would affect absorption of metformin
8. Concurrent illness (other than LFS) that could result in life expectancy of <5 years
9. History of the following cardiac conditions:
9.1. Congestive cardiac failure of >Grade II severity according to the New York Heart Association Functional Classification (defined as symptomatic at less than ordinary levels of activity).
9.2. Ischaemic cardiac event including myocardial infarction within 3 months prior to date of enrolment.
9.3. Uncontrolled cardiac disease,including unstable angina pectoris,uncontrolled hypertension (i.e.,sustained systolic BP >160 mmHg or diastolic BP >90 mm Hg)
10. Evidence of significant renal impairment eGFR <50ml50ml/minute/1.73m² (those with eGFR between 50-60ml/minute/1.73m² are eligible to enter but, if in the metformin arm, will undergo modified dose-titration)
11. Liver cirrhosis and/or alkaline phosphatase,aspartate transaminase or alanine transaminase >2.5 x upper limit of normal (ULN)
12. Elevated risk of lactic acidosis such as current chronic alcoholism,congenital lactic acidosis, concurrent intake of carbonic anhydrase inhibitor (e.g. acetazolamide)
13. Known allergy to metformin
14. Does not fulfil MRI Safety Screening criteria (e.g. implanted cardiac pacemaker, post-surgical metal hardware – plates etc) and/or unable to undergo baseline scan.

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Previous exclusion criteria:

1. Currently taking metformin
2. Metformin intake for more than 3 months in total, within the 2 years antecedent to the date of trial enrolment
3. Completion of cancer systemic therapy within the 6 months antecedent to the date of trial enrolment
4. Current type 1 or 2 diabetes mellitus
5. Presence of ongoing active cancer (detected previously or at baseline scanning)
6. Current pregnancy or lactation
7. Gastro-intestinal condition (such as short-bowel syndrome) that could affect uptake of metformin
8. Concurrent illness (other than LFS) that could result in life expectancy of <5 years
9. History of the following cardiac conditions:
9.1. Congestive cardiac failure of >Grade II severity according to the New York Heart Association Functional Classification (defined as symptomatic at less than ordinary levels of activity).
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13. Known allergy to metformin
14. Does not fulfil MRI Safety Screening criteria (e.g. implanted cardiac pacemaker, post-surgical metal hardware – plates etc) and/or unable to undergo baseline scan.

Date of first enrolment
20/12/2023

Date of final enrolment
31/03/2026

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
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OX3 9DU

Study participating centre
Guys and St Thomas' NHS Foundation Trust
249 Westminster Bridge Road
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SE1 7EH

Study participating centre
Addenbrookes Hospital
Cambridge University Hospitals NHS Foundation Trust
Hills Road
Cambridge
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CB2 0QQ

Study participating centre
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Nottingham
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NG5 1PB

Study participating centre
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Foresterhill Road
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AB25 2ZN

Study participating centre
University Hospital Southampton NHS Foundation Trust
Southampton General Hospital
Tremona Road
Southampton
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SO16 6YD

Study participating centre
University Hospitals of Leicester NHS Trust
Leicester Royal Infirmary
Infirmary Square
Leicester
England
LE1 5WW

Study participating centre
Western General Hospital
Crewe Road South
Edinburgh
Lothian
Scotland
EH4 2XU

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
George Pantziarka TP53 Trust

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		03/02/2024	09/02/2024	Yes	No
Participant information sheet	version 4.0	24/07/2024	31/03/2025	No	Yes
Participant information sheet	version 2.0	01/09/2023	08/04/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes