ISRCTN12205320 https://doi.org/10.1186/ISRCTN12205320

# Randomized multi-country adaptive phase IIb platform trial evaluating treatments for Crimean-Congo haemorrhagic fever (UMIT-2 Trial)

**Submission date**
05/03/2026

**Recruitment status**
Recruiting

**Registration date**
11/03/2026

**Overall study status**
Ongoing

**Last Edited**
11/03/2026

**Condition category**
Infections and Infestations

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

## Plain English summary of protocol

Background and study aims
Crimean-Congo haemorrhagic fever (CCHF) is a serious viral infection that can spread between people and often causes severe illness or death. In some outbreaks, between 5% and 40% of people with the disease die, especially where medical care is limited. Most recent cases have occurred in Türkiye and Iraq, and the infection is now considered an important emerging global health threat.
There are currently no medicines proven to treat CCHF, and care mainly focuses on supporting patients — for example, by treating symptoms and managing complications.
The UMIT-2 trial (UMIT means “hope” in Turkish) is the first large study to test whether antiviral medicines can help people recover from CCHF. The study will take place in several hospitals in Türkiye and Iraq between 2026 and 2028.

Who can participate?
Adult inpatients (≥18 years) hospitalised with laboratory-confirmed CHFV infection.

What does the study involve?
Participants who agree to take part will be randomly placed into one of three groups:
• Standard care alone
• Favipiravir
• Ribavirin
Treatment will last about one week while the participant is in the hospital, and they will then be followed up for around one month.
These medicines aim to help the body remove the virus more quickly, as people with the most severe disease often have higher levels of the virus in their blood for longer. The UMIT-2 trial uses an adaptive design, which means that treatment groups can be stopped early if they do not work, or new treatments can be added as more evidence becomes available. If new treatments are added in the future, these will only be introduced after review and approval by ethics committees and regulatory authorities.

What are the possible benefits and risks of participating?
The results from UMIT-2 will help doctors and scientists understand which antiviral medicines are most effective against CCHF, improve treatment for patients, and guide future research into this dangerous disease.

Taking part in the UMIT-2 clinical trial does not present specific disadvantages beyond the potential side effects of the study medicines and the time commitment required for follow-up visits, including the Day 28 assessment. All medicines can cause side effects, although not everyone will experience them. Participant safety will be closely monitored throughout the study with regular clinical assessments and blood tests. Favipiravir is generally well tolerated but may cause mild gastrointestinal symptoms (such as nausea, vomiting, diarrhoea, or stomach pain), headache, dizziness, skin rash, or temporary changes in liver function tests or uric acid levels. Ribavirin has been used for many years to treat viral infections but can sometimes cause anaemia (a reduction in red blood cells), which may lead to tiredness or shortness of breath, as well as nausea, vomiting, reduced appetite, fever, chills, headache, muscle pain, or mood changes such as anxiety or irritability. Study procedures are similar to those used in routine hospital care for CCHF and include blood tests, physical examinations, monitoring of vital signs, throat or nose swabs, and reviews of medicines and symptoms. These procedures may cause brief discomfort, minor bruising from blood sampling, or short-lasting irritation from swabs. Study treatment may be stopped if it is considered not beneficial or not safe to continue.

Where is the study run from?
Liverpool School of Tropical Medicine, UK.

When is the study starting and how long is it expected to run for?
May 2026 to December 2027

Who is funding the study?
Medical Research Council (MRC), UK.

Who is the main contact?
umit@lstmed.ac.uk

# Contact information

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Public

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## Additional identifiers

### ClinicalTrials.gov (NCT)
NCT06860334

## Study information

### Scientific Title
UMIT-2: a randomized, multi-country, adaptive phase iib platform trial to determine the efficacy and safety of therapeutics for crimean-congo haemorrhagic fever

### Acronym

UMIT-2

## Study objectives
Primary Objectives:
To compare CCHFV viral dynamics of investigational therapeutics relative to the control arm
Secondary Objectives:
To determine the safety and tolerability of investigational therapeutics relative to the control arm
To compare time to successful hospital discharge between participants receiving investigational therapeutics, relative to the control arm
To evaluate antiviral efficacy of investigational therapeutics
To compare the overall mortality in patients with CCHF who receive different investigational therapeutics with those who receive the control arm
To compare mortality rates among patients whose baseline predictors of disease place them in different categories for disease severity, who receive different investigational therapeutics.
To characterise the plasma pharmacokinetics (PK) of therapeutics in CCHF
Exploratory Objectives:
To characterise virus, host immune response and viral resistance over time

## Ethics approval required
Ethics approval required

## Ethics approval(s)
1. submitted 05/03/2026, Liverpool School of Tropical Medicine: Research Ethics Committee (LSTM REC W-2-037, 1st Floor, Wolfson Building, LSTM, Pembroke Place, Liverpool, L3 5PH, United Kingdom; +44 151 702 9587; lstmrec@lstmed.ac.uk), ref: 25-013

2. approved 05/03/2026, Samsun Ondokuz Mayis University Ethical Committee (Körfez, Ondokuz Mayıs Ünv, 55270 Atakum/Samsun, Samsum, 55270, Türkiye; +90 31211919; samsunkaek@omu.edu.tr), ref: KAD-FR-42

## Primary study design
Interventional

## Allocation
Randomized controlled trial

## Masking
Open (masking not used)

## Control
Active

## Assignment
Parallel

## Purpose
Treatment

## Study type(s)

## Health condition(s) or problem(s) studied
Adult in-patients (≥18 years) hospitalised with laboratory confirmed CHFV infection by positive polymerase chain reaction (PCR) test.

## Interventions
Description of randomisation: Participants will be randomised in a 1:1:1 ratio to one of three initial trial arms: standard of care, investigational antiviral A, or investigational antiviral B. Randomisation will be stratified by country to account for potential geographic differences in disease presentation, healthcare delivery, or standard treatment practices.

Arm A: Optimised Standard of Care

Arm B: Favipiravir: 6-fluoro-3-hydroxypyrazine-2-carboxamide, T-705 (Intravenous and oral tablet formulations). IV Favipiravir 2400mg BD on day 1, Day 2 IV Favipiravir 1200mg BD, Day 3-7 PO Favipiravir 1200mg BD

Arm C: Ribavirin: 1-3,4-dihydroxy-5-1,2,4-triazole-3-carboxamide (tablet formulation). Ribavirin will be given at standard dosing: Day 1 PO Ribavirin 33mg/kg (load dose) then 16mg/kg QDS, Day 2 PO Ribavirin 16mg/kg QDS, Day 3-5 PO Ribavirin 16mg/kg QDS, Day 6 to 7 PO Ribavirin 8mg/kg TDS.

## Intervention Type
Drug

## Phase
Phase II

## Drug/device/biological/vaccine name(s)
IV Favipiravir, Oral Favipiravir, Oral Ribavirin

## Primary outcome(s)
1. CCHFV viral dynamics measured using Proportion of patients with undetectable CCHF viral RNA in blood by day 7 at Baseline and Day 7

## Key secondary outcome(s))
1. Safety and tolerability measured using Incidence of serious adverse events and Frequency and characterisation of clinically significant (Grade 3 and above) adverse events related to study agent administration at Baseline, Daily during hospitalisation and Day 28

2. Hospital discharge measured using Time from randomisation to discharge from hospital at Baseline and Hospital discharge

3. Antiviral efficacy measured using CCHFV viral load reduction by PCR at Baseline, Day 3, 5, 7 and day 28.

4. Mortality rates measured using All-cause mortality at Day 14 and 28

5. Plasma pharmacokinetics (PK) measured using Concentrations of investigational therapeutics in plasma at Day 3 and 5

## Completion date

31/12/2027

# Eligibility

### Key inclusion criteria
1. Adult in-patients (≥18 years) at the time of screening.
2. Confirmed CCHF infection: Laboratory confirmed CCHF infection defined as positive polymerase chain reaction (PCR) test within 5 days prior to randomisation
3. Ability to provide informed consent signed by study patient or legally acceptable representative (for illiterate individuals).
4. Women of childbearing potential (WOCBP) and male patients who are sexually active with WOCBP must agree to use a highly effective method of contraception.
5. Severity Grading System (SGS) for CCHF – Low/moderate risk. (Appendix 15)
6. Less than or equal to 7 days from onset of CCHF symptoms
7. Willingness to participate in the full protocol
8. Requirement to be hospitalised for treatment

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 years

### Upper age limit
100 years

### Sex
All

### Total final enrolment
0

### Key exclusion criteria
1. Severe renal impairment: Stage 4 severe chronic kidney disease or requiring dialysis (i.e., estimated glomerular filtration (eGFR) rate <30 mL/min/1.73 m2)
2. Pregnant or breast feeding
3. Anticipated transfer to another hospital which is not a study site within 72 hours
4. Known Allergy to any study medication
5. Patients participating in another clinical trial of an investigational medicinal product (CTIMP) within the last 30 days.
6. Known hypersensitivity or allergy to any component of the investigational medicinal product (IMP) or its excipients or documented previous intolerance or significant adverse reaction to the active IMP.
7. Participation in another clinical trial involving an investigational medicinal product (CTIMP) within 30 days or five half-lives of the prior IMP (whichever is longer).
8. Any condition or circumstance which, in the opinion of the Investigator, would place the participant at undue risk, compromise safety, or interfere with trial participation or

interpretation of results.
9. Severity Grading System (SGS) for CCHF – High risk (Appendix 15)
10. Patients taking the drugs listed below within 30 days or 5 times the half-life (whichever is longer) of enrolment:
10.1. Pyrazinamide
10.2. Repaglinide
10.3. Theophylline
10.4. Famciclovir, Sulindac

### Date of first enrolment
01/05/2026

### Date of final enrolment
30/09/2027

## Locations

### Countries of recruitment
Iraq

Türkiye

### Study participating centre
**Ondokuz Mayıs Üniv**
Türkiye

### Study participating centre
**Sivas Cumhuriyet Üniv.**
Türkiye

### Study participating centre
**Erzurum Şehir Hast.**
Türkiye

### Study participating centre
**Erzurum Atatürk Üniv.**
Türkiye

### Study participating centre
**Ankara Şehir Hastanesi**
Türkiye

# Sponsor information

**Organisation**
Liverpool School of Tropical Medicine

**ROR**
https://ror.org/03svjbs84

# Funder(s)

**Funder type**

**Funder Name**
Medical Research Council

**Alternative Name(s)**
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**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