Pragmatic Optimized Rifampicin Trial

NCT06057519

Status	RECRUITING
Phase	Phase 3
Sponsor	Radboud University Medical Center
Enrollment	164 participants

Key Eligibility Criteria

Inclusion (6)

- The patient has provided informed consent for study participation prior to all trial-related procedures.
- The patient has a diagnosis of pulmonary tuberculosis according to the local diagnostic criteria.
- The patient is aged 18 years or older at the day of informed consent.
- No known allergic reactions or toxicity to rifampicin in the past.
- Female patients of childbearing potential must have a negative serum pregnancy test, and consent to practice an effective method of birth control during the study. And they should not be lactating during the trial (female participants of childbearing potential only). Effective birth control for female patients has to include two methods, including methods that the patient's sexual partner(s) use. At least one must be a barrier method. Female patients are considered not to be of childbearing potential if they are post-menopausal with no menses for the last 12 months, or surgically sterile (this condition is fulfilled by bilateral oophorectomy, hysterectomy, and by tubal ligation which is done at least 12 months prior to enrolment).

... and 1 more (see full listing online)

Exclusion (21)

- The patient has tuberculosis which is assessed to receive high dose rifampicin according to the local standard of care.
- The patient started current TB treatment more than 4 weeks ago.
- The patient has TB meningitis.
- The patient is in a coma.
- Circumstances that raise doubt about free, uncoerced consent to study participation (e.g. in a prisoner or mentally handicapped person)

... and 16 more (see full listing online)

Locations (2 total)

ASL Città di Torino, Turin, Italy
Radboud University Medical Centre, Nijmegen, Netherlands