

Prevention of Ototoxicity in NTM Patients Treated With IV Amikacin

NCT05730283

Status	RECRUITING
Phase	Phase 2
Sponsor	Kevin Winthrop
Enrollment	105 participants

Key Eligibility Criteria

Inclusion (9)

- Providing informed consent, documented by signing and dating the currently valid informed consent form.
- Considered by the Investigator to have unimpaired consent capacity, without reliance on a legally authorized representative.
- Stated willingness and ability to comply with study procedures and availability for the duration of the study.
- Aged ≥ 18 and < 80 .
- NTM infection meeting current Pulmonary NTM guidelines from the American Thoracic Society and the Infectious Diseases Society of America (ATS/IDSA) for systemic (IV) aminoglycoside therapy.

... and 4 more (see full listing online)

Exclusion (22)

- Received a systemic aminoglycoside antibiotic within 6 months prior to planned first dose of amikacin.
- ECG at Screening or prior to randomization (mean of triplicate values) with QT interval corrected using Fridericia's formula (QTcF interval) ≥ 450 msec.
- ECG at Screening or prior to randomization with abnormalities that, in the Investigator's judgment, might predispose patient to clinically significant arrhythmia.
- Patients taking strong CYP3A4 inducers such as rifampin and rifabutin in the 7 days prior to randomization or have the need for ongoing treatment with concomitant oral or intravenous therapy with strong CYP3A4 inducers during the study. If an additional antibiotic is needed, then azithromycin will be used.
- Patients taking strong CYP3A4 inhibitors such as clarithromycin in the 7 days prior to randomization or the need for ongoing treatment with concomitant oral or intravenous therapy with strong CYP3A4 inhibitors during the study. If an additional antibiotic is needed, then azithromycin will be used.

... and 17 more (see full listing online)

Locations (5 total)

National Jewish Health, Denver, Colorado, United States
Mayo Clinic, Rochester, Minnesota, United States
Oregon Health & Science University, Portland, Oregon, United States
... and 2 more locations

<https://clinicaltrials.gov/study/NCT05730283>

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