Main

Note: This record shows only 22 elements of the WHO Trial Registration Data Set. To view changes that have been made to the source record, or for additional information about this trial, click on the URL below to go to the source record in the primary register.

Register:	ClinicalTrials.gov
Last refreshed on:	28 November 2022
Main ID:	NCT03320018
Date of registration:	20/10/2017
Prospective Registration:	Yes
Primary sponsor:	Stony Brook University
Public title:	Neuroprotection in Acute Ischemic Stroke H2M
Scientific title:	Pilot Study of the Neuroprotective Effects of Hydrogen and Minocycline in Acute Ischemic Stroke
Date of first enrolment:	August 2, 2017
Target sample size:	100
Recruitment status:	Recruiting
URL:	https://clinicaltrials.gov/show/NCT03320018
Study type:	Interventional
Study design:	Allocation: Randomized. Intervention model: Parallel Assignment. Primary purpose: Treatment. Masking: Triple (Participant, Care Provider, Outcomes Assessor).
Phase:	Phase 2/Phase 3

Countries of recruitment

United States

Contacts

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Affiliation:		**Affiliation:**		**Affiliation:**	Stony Brook University Hospital

Key inclusion & exclusion criteria

Inclusion Criteria:

1. Aged 18 years old or over

2. Presenting to/at Stony Brook University Hospital with acute ischemic stroke

3. Baseline (at admission to study) National Institute of Health Stroke Scale (NIHSS) of = 5

4. Administration of study medication possible within 24 hours of last known well

Exclusion Criteria:

1. Pre-existing neurological disability (historical NIHSS > 3); unable to live independently 3. Severe stroke or comorbidities likely to result in patient dying within 3 months 4. Acute or chronic renal failure with calculated creatinine clearance < 30 5. Liver disease leading to > 3x elevation in liver transaminases or significant loss of synthetic capacity* 6. Thrombocytopenia (<100x10^9platelets / L blood) 7. Pre-existing infectious disease requiring antibiotic therapy that have a negative interaction with minocycline. (Penicillin, amoxicillin, ampicillin, bacampicillin, carbenicillin, cloxacillin, dicloxacillin, methicillin, mezlocillin, nafcillin, oxacillin, piperacillin, ticarcillin)
8. Pregnancy or nursing. Females of reproductive age will be required to use barrier contraception or abstain from sexual intercourse while on study medications, as minocycline may render oral contraceptives less effective.

9. Known allergy to tetracycline group of drugs 10. Concurrent treatment with retinoids or ergot alkaloids 11. Inability to safely tolerate the fluid load (iv normal saline or po water) associated with study medication* 12. Treatment with another investigational drug within the last 30 days that may interfere with this study's medications* 13. Inability to tolerate or comply with study procedures*

Age minimum: 18 Years
Age maximum: N/A
Gender: All

Health Condition(s) or Problem(s) studied

Stroke, Ischemic

Intervention(s)

Drug: Hydrogen

Drug: Minocycline

Other: Placebo Hydrogen

Other: Placebo Minocycline

Primary Outcome(s)

simplified modified Rankin Scale (sMRSq) [Time Frame: 90 days]

Secondary Outcome(s)

NIH Stroke Scale (NIHSS) [Time Frame: 90 days]

simplified modified Rankin Scale (sMRSq) [Time Frame: 45 days]

Secondary ID(s)

932805

Source(s) of Monetary Support

Please refer to primary and secondary sponsors

Secondary Sponsor(s)

Ethics review

Results

Results available:

Date Posted:

Date Completed:

URL: