

Strategic Research Program

Project Proposal

Thrombolysis for Acute Ischemic Stroke facilitated
by TeleStroke: Oman TeleStroke Initiative

Brief title: TeleStrokeOman

Informed Consent Form

Information to Study Participants & Documentation of Verbal Consent

(Submission: 1st Feb 2023)

Official ID:

RC/SR-MED/MEDI/23/02

Supplementary ID:

By Institutional Ethics Committee

SQU-EC/ 619/2021 MREC #2641

Non-Communicable Diseases: Strategic Research Program

Sultan Qaboos University / Ministry of Health, Oman.

Title of Study: **TeleStroke Oman: *Efficacy of TeleStroke Services linking underserved Hospitals in Oman.***

Project Number:

Approval No. under Ethics Committee-SQU:

Approval No. under Ethics Committee-Moh:

Information to Study Participants:

- Ischemic Stroke is a condition occurring due to sudden decrease in blood supply to a localized part of the brain. It has several risk factors including advancing age, hypertension, diabetes mellitus, smoking, high lipid levels, etc.
- Stroke is a major cause of significant disability and mortality in most countries, including Oman.
- In addition to conventional management of Stroke, emergent administration of a medication -IV alteplase - within 4.5 hours of stroke onset under guidance by a Neurologist is known to be associated with improved outcomes. One-third (32%-46%) higher proportion of patients may experience minimal or no disabilities.
- This treatment is a standard of care, recommended by most Stroke treatment guidelines (including Oman guidelines).
- However, such treatment is IV alteplase is known to be associated with bleeding/hemorrhage in up to 6.5% of patients; half of these may be in/around the brain. Mortality in up to half of patients with severe hemorrhage is reported.
- Such adverse effects are off-set by the significantly higher proportion of patients in whom death or disability is reduced/avoided.

- This project attempts to enable a Neurologist to examine patients with acute stroke urgently, using a special tele-conference system. By this method, patients who may benefit with such treatment can be recognized and administered the medication even in peripheral hospitals (such as yours) where a Neurologist is not available on-site.
- You will be informed of the nature and details of stroke experienced by you OR your family member by the attending Doctor/Neurologist. You will also be informed if administering IV alteplase is indicated in such situation.
- Your consent is request for administering this medication emergently, as a step in providing optimal care.

If you have any further inquiries, you may contact Investigators who oversee this project:

Name	Email	Phone
1.		
2.		
3.		

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Documentation of Verbal Consent

Date:

Patient Name:

ID Number:

Hospital:

Diagnosis:

This is to document that the above mentioned patient OR his Care-giver was informed about the indication to receive Inj Alteplase intravenously as part of his emergent treatment for acute ischemic stroke. Known benefits and adverse effects were described.

The indication for IV alteplase and contraindications were reviewed with Neurologist by TeleStroke facility.

This is to confirm that this patient OR his Care-giver consented to his receiving IV Alteplase.

Emergency Physician: Name:

Signature:

Date / Time:

Verbal consent witnessed by: Name:

Signature:

Date/time