HALT-IT- tranexamic acid for the treatment of gastrointestinal bleeding: study protocol for a randomised controlled trial

Data Creators

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Data Description

Documentation associated with the HALT-IT trial, a pragmatic, randomised, double-blind, placebo-controlled trial which will determine the effect of tranexamic acid on mortality, morbidity (re-bleeding, non-fatal vascular events), blood transfusion, surgical intervention, and health status in patients with acute gastrointestinal bleeding.

Data Collection Methods

A full description of the study protocol is provided at http://researchonline.lshtm.ac.uk/2026593/ and http://dx.doi.org/10.1186/1745-6215-15-450.

Data Analysis and Preparation

See above

Geographic regions

United Kingdom

Key dates

Patients will enter the trial from January 2013 until October 2016.

Quality Controls

See study protocol

Species:

Human population

Privacy:

See study protocol

Ethics

A list of ethics bodies that have approved the study can be found in '13063_2014_2322_MOESM6_ESM.docx', available at http://dx.doi.org/10.1186/1745-6215-15-450.

Keywords

Gastrointestinal bleeding, Tranexamic acid, Clinical trials

Language of written material

English

Project Information

Project

HALT-IT: Haemorrhage ALleviation with Tranexamic acid IntesTinal system

Funder/Sponsor

The HALT-IT trial is funded by the National Institute for Health Research Health Technology Assessment programme. Funding for this trial covers trial materials, meetings and central organisational costs.

Grant Number

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Associated Roles

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File Description

Title	Filename	File type	Description
Study Entry form	File1-StudyEntryForm.pdf	Adobe PDF 1.4	Entry form used to assess eligibility and collect baseline information for the study
Outcome Form	File2-OutcomeForm.pdf	Adobe PDF 1.4	Short Outcome form to be completed from medical records within 28 days after randomisation, on discharge from randomising hospital, or on death (whichever occurs first)
Short Information Leaflet	File3-SummarySheet.pdf	Adobe PDF 1.4	Short information leaflet on the trial provided to the patient and, if present, their relatives, prior to enrolment
Trial Information Sheet	File4-InformationSheet.pdf	Adobe PDF 1.4	Trial information sheet to be provided to the patient
Consent Form	File5-ConsentForm.pdf	Adobe PDF 1.4	Consent sheet. If the patient cannot read or write, the information sheet may be read to them and they may mark the form with a cross or thumbprint. Witnesses not associated with the trial must provide a full signature confirming the mark)