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Observational / Interventions Research Ethics Committee

Professor Haleema Shakur-Still
LSHTM

17 April 2020

Dear Haleema

Study Title: A randomised controlled trial to assess the pharmacokinetics and pharmacodynamics of intramuscular, intravenous and oral administration of tranexamic acid in women giving birth by caesarean section

LSHTM Ethics Ref: 21255

Thank you for responding to the Interventions Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Other	Ian Roberts_GCP Certificate_Sept2016	01/09/2016	1
Other	Haleema Shakur-Still_GCP Certificate_Sept2016	30/09/2016	1
Investigator CV	Rizwana Chaudhri CV 10-05-2018	10/05/2018	1
Investigator CV	Haleema Shakur-Still_CV_August 2018	01/08/2018	1
Investigator CV	Ian Roberts_CV_2018	01/08/2018	1
Investigator CV	CV Stanislas Grassin Delyle	01/08/2018	1
Other	Dr Rizwana Chaudhri	23/11/2018	1
Other	Stanislas Grassin Delyle_ GCP (2)	18/12/2018	1
Protocol / Proposal	Appendix 2 Consent procedure overview	17/01/2020	1.0
Information Sheet	Appendix 2 Consent procedure overview	17/01/2020	1.0
Sponsor Letter	2020-KEP-401_Sponsor Confirmation_30.01.20	30/01/2020	1
Information Sheet	Participant information sheet and consent form v1	31/01/2020	1
Protocol / Proposal	1. WOMAN-PharmacoTXA_protocol_v1.0 (1)	31/01/2020	1.0
Protocol / Proposal	Appendix 1 Participant information sheet and consent form v1	31/01/2020	1.0
Protocol / Proposal	WomanPTXA CRF booklet v1.0 31_01_2020docx	31/01/2020	1.0
Safety Information	WPTXA IB v1.0 31 01 2020	31/01/2020	1.0

Protocol / Proposal	WPTXA Alert card	31/01/2020	1.0
Protocol / Proposal	1b TC WOMAN-PharmacoTXA_protocol_v1.0 with tracked changes	31/01/2020	1.0 with tracked cha
Protocol / Proposal	Appendix 1 Participant information sheet and consent form v1.0 with tracked changes	31/01/2020	1.0 tracked changes
Information Sheet	Appendix 1 Participant information sheet and consent form v1.0 with tracked changes	31/01/2020	1.0 tracked changes
Safety Information	WPTXA IB _v1.0_31 01 2020 tracked changes (1)	31/01/2020	1.0 tracked changes
Safety Information	WPTXA IB _v1.1_17 02 2020 (1)	17/02/2020	1.1
Protocol / Proposal	1b WOMAN-PharmacoTXA_protocol_v1.1	19/02/2020	1.1
Protocol / Proposal	1a TC WOMAN-PharmacoTXA_protocol_v1.1 with tracked changes	19/02/2020	1.1 tracked changes
Protocol / Proposal	Appendix 1 Participant information sheet and consent form v1 1	03/03/2020	1.1
Information Sheet	Appendix 1 Participant information sheet and consent form v1 1	03/03/2020	1.1
Protocol / Proposal	WPTXA Alert Card_v1.1 highlighted changes	06/03/2020	1.1
Protocol / Proposal	WPTXA Alert Card_v1.1	06/03/2020	1.1
Protocol / Proposal	1a WOMAN-PharmacoTXA_protocol_v1.2	03/04/2020	1.2
Covering Letter	Response to LSHTM_Ethics_WPHTXA	06/04/2020	1
Protocol / Proposal	WomanPTXA CRF booklet v1.3 - Pakistan - highlighted changes (with footer) (1)	09/04/2020	1.3
Protocol / Proposal	WomanPTXA CRF booklet v1.3 - Pakistan (with footer) (1)	09/04/2020	1.3
Protocol / Proposal	WomanPTXA CRF booklet v1 3 - Zambia - highlighted changes (with footer) (1)	09/04/2020	1.3
Protocol / Proposal	WomanPTXA CRF booklet v1.3 - Zambia (with footer) (1)	09/04/2020	1.3

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

An annual report should be submitted to the committee using an Annual Report form on the anniversary of the approval of the study during the lifetime of the study.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk

Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,

Professor Jimmy Whitworth
Chair

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