

London School of Hygiene & Tropical Medicine

Keppel Street, London WC1E 7HT

United Kingdom

Switchboard: +44 (0)20 7636 8636

www.lshtm.ac.uk

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MEDICINE



Observational / Interventions Research Ethics Committee

Prof Haleema Shakur-Still
LSHTM

1 May 2020

Dear Haleema

Study Title: Aspirin, losartan and simvastatin in hospitalised COVID-19 patients: a multinational randomised open-label factorial trial

LSHTM Ethics Ref: 21960

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	Haleema Shakur-Still_GCP Certificate_Sept2016	06/09/2016	1.0
Other	Ian Roberts_GCP Certificate_Sept2016	06/09/2016	1.0
Investigator CV	CV_Haleema Shakur-Still_Mar2019	01/03/2019	1.0
Safety Information	COZAAR 100 mg Film-Coated Tablets - Summary of Product Characteristics (SmPC) (emc)	25/06/2019	1.0
Safety Information	Aspirin 75mg Tablets - Summary of Product Characteristics (SmPC) (emc)	04/12/2019	1.0
Safety Information	Simvastatin 80mg Tablets - Summary of Product Characteristics (SmPC) (emc)	09/03/2020	1.0
Sponsor Letter	2020-KEP-420_sponsor_CRASH19_09042020	09/04/2020	1.0
Information Sheet	Information sheet and consent forms Version 0.4_15 April 20_Generic	15/04/2020	0.4
Investigator CV	CV_Ian Roberts_2019	16/04/2020	1.0
Covering Letter	Cover Letter_Ethics Clarification response_FINAL 230420 v1.0	23/04/2020	1
Protocol / Proposal	CRASH-19 Version 1.0 Protocol 23April2020_International version_CLEAN	23/04/2020	1
Protocol / Proposal	CRASH-19 Version 1.0 Protocol 23April2020_International version_Tracked changed	23/04/2020	1.0
Covering Letter	TSC Letter of Support CRASH-19_28 April 2020	28/04/2020	1
Covering Letter	Cover Letter_Ethics Clarification response_FINAL 280420 v1.0	28/04/2020	1

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.

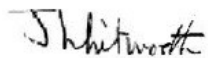
An annual report should be submitted to the committee using an Annual Report form on the anniversary of the approval of the study during the lifetime of the study.

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

ethics@lshtm.ac.uk
<http://www.lshtm.ac.uk/ethics/>

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