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NOTA DINAS
Nomor: ND-[561 /UN2.F1/ETIK/PPM.00.02/2020

Kepada : dr. Erni Juwita Nelwan, PhD, SpPD, K-PTI, FACP-FINASIM
Institusi : Peneliti Utama Departemen Ilmu Penyakit Dalam FKUI-RSCM
Dari : Komite Etik Penelitian Kesehatan FKUI-RSCM
Hal : Amandemen Protokol Penelitian

Sehubungan dengan protokol penelitian berikut :
"**Randomised Evaluation of Covid-19 Therapy (RECOVERY).**"

Peneliti Utama : dr. Erni Juwita Nelwan, PhD, SpPD, K-PTI, FACP-FINASIM
No. Protokol Etik : 20-11-1405
No. Surat Kaji Etik : KET-1360/UN2.F1/ETIK/PPM.00.02/2020 tanggal 16 November 2020

Komite Etik Penelitian Kesehatan FKUI-RSCM telah menerima dan meninjau surat Sejawat:

Tanggal	Nomor Surat	Perihal	Keterangan
10 Desember 2020	-	Pengajuan amandemen Protokol ver11.2 tanggal 01 Dec 2020 dan PIS/ICF Bahasa ver 2.0 tanggal 30 Nov 20 terakit Penelitian RECOVERY (FKUI Ref No. 20-11-1405)	1. Protokol RECOVERY versi 11.2 dated 01 December 2020, 1 kopi 2. PIS ICF version 10.1 dated 21 November 2020, 1 kopi 3. PIS ICF versi Bahasa Indonesia 2.0 tanggal 30 November 2020
Isi Amandemen : **Terlampir**			

Komite Etik Penelitian Kesehatan FKUI-RSCM dapat menyetujui permohonan amandemen pada protokol penelitian tersebut.

Atas laporan dan kerjasamanya, kami ucapkan terima kasih.

21 Desember 2020
Ketua KEPK FKUI-RSCM

Prof. dr. Rita Sita Sitorus, Ph.D., Sp.M(K)

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Lampiran Amandemen Study RECOVERY

Bab/Hal	Versi 10 (26 Oct 2020)	Versi 11.2 (01 Dec 2020)	Alasan
Section 1.2. Treatment Options (Page 5 of page 43)	Randomisation part A: Eligible patients may be randomly allocated between the following treatment arms: • No additional treatment • Azithromycin	Randomisation part A: Eligible patients may be randomly allocated between the following treatment arms: • No additional treatment • Colchicine (men ≥18 years old and women ≥55 years old only)	Arm azitromisin dihilangkan dan penambahan arm kolkisin ke dalam randomisasi bagian A berikut dengan penjelasan mekanisme kerja dan keterangan lain yang terkait.
Section 2.4 Main Randomisation part A (page 10 of 43)	2.4.1 Main randomisation part A: Eligible patients may be randomised to one of the arms listed below. The doses in this section are for adults. Please see Appendix 3 for paediatric dosing. Study treatments do not need to be continued after discharge from hospital. • No additional treatment • Azithromycin 500mg by mouth (or nasogastric tube) or intravenously once daily for 10 days.	2.4.1 Main randomisation part A: Eligible patients may be randomised to one of the arms listed below. The doses in this section are for adults. Please see Appendix 3 for paediatric dosing. Study treatments do not need to be continued after discharge from hospital. • No additional treatment • Colchine 1 mg after randomisation followed by 500mcg 12 hours later and then 500 mcg twice daily by mouth or nasogastric tube for 10 days in total. (Men ≥18 years old and women ≥55 years old only.)	Arm azitromisin dihilangkan dan penambahan arm kolkisin ke dalam randomisasi bagian A berikut dengan penjelasan mekanisme kerja dan keterangan lain yang terkait.
Section 2.4.1 Main Randomisation part A (Page 10 of 43) Part C (Page 11 of 43)	For randomisation part A, the randomisation program will allocate patients in a ratio of 2:1 between the no additional treatment arm and each of the other arms available. Hence if 5 arms are available, then the randomisation will be in the ratio 2:1:1:1:1 None	For randomisation part A, the randomisation program will allocate patients in a ratio of 1:1 between the no additional treatment arm and each of the other arms available The randomisation program will allocate patients in a ratio of 1:1 between the arms being evaluated in part C of the main randomisation.	Perubahan pada rasio randomisasi utama bagian A dan C menjadi 1:1
Section 1.2. Treatment Options dan Section 2.4.1 Main Randomisation part A (Page 5 and 10 of page 43)		• Colchicine (men ≥18 years old and women ≥55 years old only) • Colchine 1 mg after randomisation followed by 500mcg 12 hours later and then 500 mcg twice daily by mouth or nasogastric tube for 10 days in total. (Men ≥18 years old and women ≥55 years old only.)	Penambahan penjelasan batas usia pemberian kolkisin (pria diatas usia 18 tahun dan wanita diatas usia 55 tahun sehubungan adanya kemungkinan kontra-indikasi jika diberikan pada wanita dibawah 55 tahun.
2.4.3 Main Randomisation Part C (Page 11 of 43)	• Aspirin 150 mg by mouth (or nasogastric tube) or per rectum once daily until discharge.	• **Aspirin** 150 mg by mouth (or nasogastric tube) or per rectum once daily until discharge.[1] **[1] In countries where 150mg aspirin is not available, up to 162mg may be used instead**	Penambahan dosis modifikasi aspirin, jika dosis 150 mg tidak tersedia. Hal ini berlaku di Vietnam dan Indonesia dimana dosis yang tersedia untuk aspirin adalah 100 mg, 80 mg dan 500 mg. Karena dosis 80 dan 100 mg berupa enteric coated tablet, maka tablet tidak dapat dipotong. Dengan demikian, dosis yang akan digunakan di Indonesia adalah 160mg (80mg x 2 ECT/hari).
Appendix 1 Information about treatment arms (Page 27 of 43)	Azithromycin: Azithromycin is a macrolide antibiotic. In addition to their antimicrobial properties, the macrolide antibiotics are known to have…..	Colchicine: Colchicine inhibits cellular transport and mitosis by binding to tubulin and preventing its polymerisation as part of the cytoskeleton transport system. As a consequence, colchicine has a wide range of anti-inflammatory effects, including inhibition of certain inflammasomes (cytosolic pattern recognition receptor	Arm azitromisin dihilangkan dan penambahan arm kolkisin ke dalam randomisasi bagian A berikut dengan penjelasan mekanisme kerja dan keterangan lain yang terkait.

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		systems that are activated in response to detection of pathogens in the cytosol).23,24	
Appendix 2 Drug Specific Contraindications and cautions (Page 30 of 43)	Azithromycin • Known prolonged QTc interval* • Co-administration with chloroquine or hydroxychloroquine • Known hypersensitivity to macrolide antibiotic	Colchicine (men ≥18 years old and women ≥55 years old only) Contraindications: • Female participants <55 years old (as contraindicated in women of child-bearing potential) • Severe hepatic impairment (defined as requiring ongoing specialist care)	Arm azitromisin dihilangkan dan penambahan arm kolkisin ke dalam randomisasi bagian A berikut dengan penjelasan mekanisme kerja dan keterangan lain yang terkait.
Appendix 4 Use of IMPs in Pregnant and Breastfeeding Women (page 35 of 43)	None	All trial drugs (except REGN-COV2) have been used in pregnant women with pre-existing medical disorders where benefits outweigh the risks to fetus or woman, including in the first trimester. The existing data related to each drug is summarized below. Colchicine Colchicine is contraindicated in pregnant or breastfeeding women. Aspirin Aspirin is widely used for the prevention of pre-eclampsia in pregnant women at increased risk of the disease..... Tocilizumab	Penambahan Appendix 4 terkait penggunaan obat studi pada wanita hamil dan menyusui
Appendix 5 Organisational Structure & Responsibilitiy (Page 39 of 43)		Independent members: **Dr Nguyen Ngo Quang (Vietnam)** **Dr. Erlina Burhan (FKUI, Jakarta, Indonesia)** **Dr. Bachti Alisjahbana (UNPAD, Bandung, Indonesia)** **Dr Pardip Gyanwali (member secretary of NHRC, Nepal)** **Dr Sudha Basnet (Nepal)** Non-independent members: **Prof. Guy Thwaites** **Prof. Jeremy Day** **Evelyne Kestelyn** **Prof. Buddha Basnyat** **Prof. Raph Hamers** **Prof. Peter Horby (RECOVERY Co-Chief Investigator)**	Penambahan daftar anggota South East Asia Steering Committee (independent dan non independent members)
PIS/ICF	**Versi 1.0 tgl 02 Nov 2020**	**Versi 2.0 tanggal 30 Nov 2020**	
Section 5 Potensi Resiko (Hal 2 dari 9)	Azitromisin dapat menyebabkan gangguan pencernaan dan kelainan hasil tes darah.	**Kolkisin dapat menyebabkan gangguan pencernaan dan kelainan hasil tes darah, termasuk jumlah sel darah yang rendah meskipun hal ini jarang terjadi, Anda akan kami pantau sebagai antisipasi.**	Arm azitromisin dihilangkan dan penambahan arm kolkisin
Section 5 Potensi Resiko (Hal 2 dari 9)	None	**Wanita di bawah usia 55 tahun tidak akan menerima kolkisin karena obat ini mungkin berbahaya apabila digunakan saat hamil atau menyusui.**	Penambahan resiko terkait penggunaan obat kolkisin pada wanita hamil dan menyusui