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LAMPIRAN



**MEDICAL AND HEALTH RESEARCH ETHICS COMMITTEE (MHREC)
FACULTY OF MEDICINE, PUBLIC HEALTH AND NURSING
UNIVERSITAS GADJAH MADA – DR. SARDJITO GENERAL HOSPITAL**



ETHICS COMMITTEE APPROVAL

Ref. No. : KE/FK/0882 /EC/2019

Title of the Research Protocol : Faktor Risiko Kegagalan Nasal *Continuous Positive Airway Pressure* pada Bayi Prematur dengan Distres Respirasi

Document(s) Approved and version : Study Protocol version 02 2019

Principle Investigator : Winda Intan Permatahati

Participating Investigator(s) : dr. Tunjung Wibowo, MPH., M.Kes., Sp.A(K).

Date of Approval : **31 JUL 2019**
(Valid for one year beginning from the date of approval)

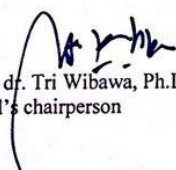
Institution(s)/place(s) of research : Instalasi Rekam Medis RSUP Dr. Sardjito

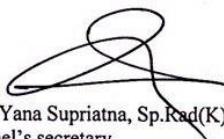
The Medical and Health Research Ethics Committee (MHREC) states that the document above meets the ethical principle outlined in the International and National Guidelines on ethical standards and procedures for researches with human beings.

The Medical and Health Research Ethics Committee (MHREC) has the right to monitor the research activities at any time.

The investigator(s) is/are obliged to submit:

- Progress report as a continuing review (state its due time)
- Report of any serious adverse events (SAE)
- Final report upon the completion of the study


Prof. dr. Tri Wibawa, Ph.D., Sp.MK(K).
Panel's chairperson


dr. Yana Supriatna, Sp.Rad(K)., Ph.D.
Panel's secretary



**MEDICAL AND HEALTH RESEARCH ETHICS COMMITTEE (MHREC)
FACULTY OF MEDICINE, PUBLIC HEALTH AND NURSING
UNIVERSITAS GADJAH MADA – DR. SARDJITO GENERAL HOSPITAL**



AMENDMENT APPROVAL

The Ethical Committee of Research in Medical Health, Faculty of Medicine, Public Health, and Nursing, has carefully reviewed the protocol entitled:

Faktor Risiko Kegagalan Nasal *Continuous Positive Airway Pressure* pada Bayi Prematur dengan Distres Respirasi

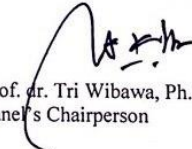
Reference Number of Ethical : KE/FK/0882/EC 31 Juli 2019
Approval Letter
Name of Principal Investigator : Winda Intan Permatahati
Name of Institution : Faculty of Medicine, Public Health, and Nursing
Universitas Gadjah Mada

And approved the submitted amendment of document :

Title of the Research Protocol : Faktor Prediktor Kegagalan Nasal *Continuous Positive Airway Pressure* pada Bayi Kurang Bulan dengan Distres Respirasi

Document(s) Approved and : Study Protocol version Amendment 2019
version
Participating Investigator(s) : 1. Dr. dr. Ekawaty Lutfia Haksari, MPH., Sp.A(K).
2. dr. Amalia Setyati, Sp.A(K).

Yogyakarta, **02 JAN 2020**


Prof. dr. Tri Wibawa, Ph.D., Sp.MK(K)
Panel's Chairperson

CASE REPORT FORM

No Register Penelitian : _____ Tanggal Pengambilan Data : _____

I. Identitas dan Demografi Pasien:

Nama pasien : _____ Identitas orang tua:
No Rekam Medis : _____ Nama ayah : _____
Jenis Kelamin : Laki-laki / Perempuan Nama ibu : _____
Tanggal Lahir : _____ No Rekam Medis Ibu:

II. Riwayat kelahiran:

Paritas : G ___ P ___ A ___ Kehamilan : Tunggal / Gemelli
Usia ibu : ___ tahun Jenis persalinan: Pervaginam / Sectio Caesarean
Usia Kehamilan : _____ minggu
Spontan/ Vakum Ekstraksi, indikasi: _____
Skor Apgar : Menit 1 : ___ Menit 5 : ___ Menit 10 : ___
Resusitasi hingga: _____
Skor Downes setelah pemberian CPAP :
Frekuensi napas: ___ Retraksi: ___ Sianosis: ___ Air entry: ___ Merintih: ___ Total:
Ventilasi tekanan positif : Ya / Tidak
Antropometri
Berat lahir : _____ gram Lingkar dada : _____ cm
Panjang badan lahir : ___ cm Lingkar perut : _____ cm
Lingkar kepala : _____ cm Lingkar lengan atas : _____ cm

III. Riwayat maternal

Ketuban pecah dini: Ya / Tidak, selama: _____ jam
Antenatal steroid : Ya / Tidak. Dosis lengkap Parsial dose
Penyulit :
 Hipertensi Penyakit Jantung Tiroid
 Diabetes Mellitus Lain-lain : _____

IV. Riwayat perawatan :

Terapi oksigen : Bubble CPAP Ventilator CPAP
Positive end-expiratory pressure : _____ mmHg
Fraction of inspired oksigen : _____ %
Hipotermia dalam 24jam pertama : Ya / Tidak
Pemberian surfaktan : Ya / Tidak. Frekuensi: _____ kali.
Metode: INSURE / MIST
Apneu of prematurity : Ya / Tidak. Onset : _____ hari

V. Pemeriksaan penunjang:

Rontgen toraks-abdomen:
 Sindrom Distres Respirasi: Derajat I Derajat II Derajat III Derajat IV

- Pneumonia
 Aspirasi mekonium
Penyakit Jantung Bawaan
Ekokardiografi : Ya / Tidak. Hasil : _____
Screening BBLR :
USG Kepala : Ya / Tidak. Hasil : _____
OAE : Ya / Tidak. Hasil : _____
Konsul mata : Ya / Tidak. Hasil : _____
- Transient tachypnea of the newborn*
 Lain-lain : _____

VI. Komorbiditas Infeksi

- Necrotizing Enterocolitis* Neonatal Sepsis Lain – lain : _____

VII. Luaran

- Gagal CPAP : Ya / Tidak. Onset : _____ jam
Intubasi : Ya / Tidak
Meninggal : Ya / Tidak. Usia