

Effectiveness of oral methylprednisolone as an additional treatment for infants with cholestasis in Dr Soetomo General Academic Hospital, Surabaya, Indonesia

Submission date 22/10/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/10/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 09/08/2024	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English Summary

Background and study aims

Cholestasis is an obstruction of bile flow which causes disruption of the secretion of various substances from the liver into the duodenum (small intestine), so that these materials are retained in the liver and cause damage. The diagnosis of cholestasis is based on clinical conditions and laboratory tests. Clinically, the baby looks yellow (jaundice) with a serum direct bilirubin level over 1.5 mg/dl and/or over 15% of the total bilirubin level. Oral corticosteroids have been used in clinical practice in infants with cholestasis and mostly give satisfactory results if given early before the baby is 2 months old. However, no randomized controlled trial (RCT) has been conducted to compare the improvement of cholestasis in infants receiving oral corticosteroids vs placebo (dummy drug). Until now there have been no publications on the use of corticosteroids as the main treatment of biliary atresia (bile duct blockage), although many experts believe that an immunological process (inflammatory and autoreactive) is the underlying cause. The aim of this study is to analyze the effect of giving oral methylprednisolone to infants with cholestasis on the improvement of jaundice, stool color, blood biochemical levels, and inflammatory markers.

Who can participate?

Patients aged 14 days to 3 months old with cholestasis

What does the study involve?

Participants are randomly allocated into two groups. The intervention group receive a combination of oral methylprednisolone (generic) and standard therapy for 14 days with dose 2 mg/kg/day in divided doses. The control group receive placebo and standard therapy for 14 days. Standard therapy given is urdalfalk 10 mg/kg/time every 8 hours.

What are the possible benefits and risks of participating?

By participating in this study, parents get information about the condition of their child's disease because a complete examination is carried out and they will be followed up on a regular basis.

Parents also get a souvenir.

There are several possible risks such as a chubby face (moon face), vomiting, diarrhea, and constipation. Drawing blood can cause risks such as pain and bruising at the needle puncture site. Even though all efforts have been made to minimize the risk in this study, there is always the possibility that undesirable things will occur, such as the child not feeling comfortable or other side effects of treatment, such as a moon face, vomiting, diarrhea, constipation, and disturbances in blood glucose levels that can occur from side effects of the treatment. Participants can withdraw from the study at any time.

Where is the study run from?

Dr Soetomo General Academic Hospital (Indonesia)

When is the study starting and how long is it expected to run for?

June 2022 to August 2023

Who is funding the study?

Kemdikbudristek (Indonesia)

Who is the main contact?

Bagus Setyoboedi, bagus.setyoboedi@fk.unair.ac.id

Study website

Not available

Contact information

Type(s)

Principal Investigator

Contact name

Dr Bagus Setyoboedi

Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

0468/KEPK/VIII/2022

Study information

Scientific Title

Effectiveness of oral methylprednisolone as adjuvant therapy on clinical improvement, biochemical markers, and inflammation in infants with cholestasis

Study hypothesis

There is an effect of oral methylprednisolone in infants with cholestasis on the improvement of jaundice, stool color, blood biochemical levels (bilirubin, aspartate aminotransferase [AST], alanine aminotransferase [ALT]), and inflammatory markers

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 15/08/2022, Ethical Committee of Dr Soetomo General Academic Hospital, Surabaya, Indonesia (Jl Prof Dr. Moestopo 6-8 Surabaya, East Java, Indonesia; +62 (0)31 5501164; kepk@rsudrsoetomo.jatimprov.go.id), ref: 0648/KEPK/VIII/2022

Study design

Single interventional double-blinded randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Condition

Cholestasis

Interventions

Subjects are randomised into two groups, namely:

1. Methylprednisolone (+)/intervention group: receive a combination of oral methylprednisolone (generic) and standard therapy for 14 days with dose 2 mg/kg/day in divided doses. After 14 days of subjects receiving methylprednisolone, the observation is completed and the patient is continued with services according to the protocol.

2. Methylprednisolone (-)/control group: receive placebo and standard therapy for 14 days. Standard therapy given is urdafalk 10 mg/kg/time every 8 hours.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Metylprednisolone (generic)

Primary outcome measure

1. Stool colour measured using stool colour card at baseline and 14 days
2. Level of AST, ALT and bilirubin measured using ELISA at baseline and 14 days
3. Level of marker inflammation (IFN- γ , IL1 β , IL2, IL4, IL6, IL10, TGF- β , ANCA) measured using ELISA at baseline and 14 days

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

22/06/2022

Overall study end date

01/08/2023

Eligibility

Participant inclusion criteria

1. Suffered from cholestasis
2. Aged 14 days to 3 months old

Participant type(s)

Patient

Age group

Mixed

Lower age limit

14 Days

Upper age limit

3 Months

Sex

Both

Target number of participants

40

Total final enrolment

40

Participant exclusion criteria

1. Suffering from congenital abnormalities
2. Suffering from genetic disorders
3. Suffering from severe infection/sepsis
4. Hemodynamic condition is unstable
5. Parents refuse to participate in research

Recruitment start date

13/10/2022

Recruitment end date

15/07/2023

Locations**Countries of recruitment**

Indonesia

Study participating centre**Airlangga University**

Jl Prof Dr Moestopo 6-8 Surabaya
Surabaya
Indonesia
60286

Sponsor information**Organisation**

Airlangga University

Sponsor details

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info@fk.unair.ac.id

Sponsor type

University/education

Website

<http://www.unair.ac.id/>

ROR

<https://ror.org/04ctejd88>

Funder(s)

Funder type

Government

Funder Name

Kementerian Pendidikan, Kebudayaan, Riset, dan Teknologi

Alternative Name(s)

Ministry of Education, Culture, Research, and Technology, Ministry of Education, Culture, Research, and Technology, Republic of Indonesia, Kemdikbudristek, Kementerian Pendidikan, Kebudayaan, Riset, dan Teknologi, Republik Indonesia, Indonesia Ministry of Education, Culture, Research, and Technology, Indonesian Ministry of Education, Culture, Research, and Technology, Kementerian Pendidikan, Kebudayaan, Riset, dan Teknologi, MECRT, Kemdikbudristek

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Indonesia

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

30/11/2022

Individual participant data (IPD) sharing plan

Raw data including the characteristics of participants and laboratory results will be shared 1 year after the study and for 2 years with a link that will be available in the journal.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/07/2024	09/08/2024	Yes	No