ISRCTN45080388 https://doi.org/10.1186/ISRCTN45080388

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

Registration date
29/10/2022

Overall study status
Completed

Last Edited
09/08/2024

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

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 urdafalk 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

Contact information

Type(s)
Principal investigator

Contact name
Dr Bagus Setyoboedi

Contact details
Jl Prof Dr. Moestopo 6-8 Surabaya
Surabaya
Indonesia
60286
+62 (0)8123560043
bagus.setyoboedi@fk.unair.ac.id

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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 objectives
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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
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(s)
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, IL1β, IL2, IL4, IL6, IL10, TGF-β, ANCA) measured using ELISA at baseline and 14 days

Key secondary outcome(s))

There are no secondary outcome measures

Completion date
01/08/2023

Eligibility

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
14 days

Upper age limit
3 months

Sex
All

Total final enrolment
40

Key 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

Date of first enrolment
13/10/2022

Date of final enrolment
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

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

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