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Impact of pharmaceutical validation on prescribing errors in a Neonatal Intensive Care Unit.

Submission date
18/11/2023

Recruitment status
No longer recruiting

Registration date
21/11/2023

Overall study status
Completed

Last Edited
21/11/2023

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Patients admitted to Neonatal Intensive Care Units (NICU) are up to eight times more at risk of medication errors than patients admitted to adult Intensive Care Units. Prescribing errors account for up to 74% of medication errors. Because of this, we have designed a project to improve the quality of care in order to reduce the number of prescription errors that reach the patient.

Who can participate?
This study is open to all newborns admitted to the intensive care unit.

What does the study involve?
We have designed a study to improve the quality of care in order to reduce medication errors in neonatal patients admitted to the intensive care unit. During this study, a clinical pharmacist will carry out a review of the treatments prescribed in the electronic prescription prior to the administration of the medication.

What are the possible benefits and risks of participating?
As this is a quality improvement project, patients can benefit from the improvement that a review of their treatment by a pharmacist can bring, without any risk.

Where is the study run from?
Hospital 12 de Octubre (Spain)

When is the study starting and how long is it expected to run for?
June 2021 to December 2022

Who is funding the study?
Hospital 12 de Octubre (Spain)

Who is the main contact?
Maria Dolores Canales, mcanales@salud.madrid.org

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
21/365

Study information

Scientific Title
Impact of pharmaceutical validation on prescribing errors in a Neonatal Intensive Care Unit. Randomised and controlled study.

Study objectives
Pharmaceutical validation of medical prescriptions reduces medication errors reaching patients admitted to neonatal intensive care units

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/10/2021, Comité de Ética de la Investigación con medicamentos del Hospital Universitario 12 de Octubre (AV Cordoba SN, Madrid, 28054, Spain; +34 91 779 26 13; ceicdoc@h12o.es), ref: 21/365

Study design
Prospective randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Safety

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Prevention of medical errors in newborns

Interventions
During the randomised phase, patients were assigned to the intervention or the control group at admission according to a simple randomisation using a web-based system (www.dcode.fr). Pharmaceutical validation of treatments was performed on a daily basis in the same way as in the pre-intervention phase for patients in the intervention group. For patients included in the control group, treatments were retrospectively reviewed at discharge from the NICU by the same pharmacist.
For all arms of the study, the follow-up time is for the duration of the patient's admission.

Intervention Type
Behavioural

Primary outcome measure
Percentage of prescription errors detected by a clinical pharmacist in e-prescribing measured at the end of the study

Secondary outcome measures
Percentage of prescribing errors reaching the patient according to the nursing administration record measured at the end of the study

Overall study start date
06/06/2021

Completion date

31/12/2022

Eligibility

Key inclusion criteria
All patients born during the study period who were admitted to the NICU and stayed for at least 24 hours and with active pharmacological treatment

Participant type(s)
Patient

Age group
Neonate

Lower age limit
0 Days

Sex
Both

Target number of participants
164

Total final enrolment
240

Key exclusion criteria
Patients admitted without pharmacological treatment or less than 24h.

Date of first enrolment
01/09/2021

Date of final enrolment
30/06/2022

Locations

Countries of recruitment
Spain

Study participating centre
Hospital 12 de Octubre
Av. Cordoba SN
Madrid
Spain
28041

Sponsor information

Organisation
Hospital Universitario 12 De Octubre

Sponsor details
Av. Cordoba SN
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Sponsor type
Hospital/treatment centre

Website
https://www.comunidad.madrid/hospital/12octubre/

ROR
https://ror.org/00qyh5r35

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hospital Universitario 12 De Octubre

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary