Clinical trial results:
Maternal and fetal serum concentrations of magnesium and maternal surveillance after administration of a 6 g bolus dose of magnesium sulfate (MgSO4) to women with imminent preterm delivery

Summary

EudraCT number	2017-004898-14
Trial protocol	SE
Global end of trial date	29 January 2020

Results information

Result version number	v1 (current)
This version publication date	18 February 2021
First version publication date	18 February 2021

Trial information

Trial identification

Sponsor protocol code	5.1-2018-12254, 2018-02-08

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Västra Götalandsregionen, Sahlgrenska Universitetssjukhuset,
Sponsor organisation address	Diagnosvägen 15, Gothenburg, Sweden, 41685
Public contact	Research Support Office, Gothia Forum, gothia.forum@vgregion.se
Scientific contact	Research Support Office, Gothia Forum, gothia.forum@vgregion.se
Sponsor organisation name	Västra Götalandsregionen, Sahlgrenska Universitetssjukhuset,
Sponsor organisation address	Diagnosvägen 15, Gothenburg, Sweden, 41685
Public contact	Ylva Carlsson, , Västra Götalandsregionen, Sahlgrenska Universitetssjukhuset, +46 313436286, ylva.carlsson@vgregion.se
Scientific contact	Ylva Carlsson, Västra Götalandsregionen, Sahlgrenska Universitetssjukhuset, +46 313436286, ylva.carlsson@vgregion.se

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	29 December 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 January 2020
Global end of trial reached?	Yes
Global end of trial date	29 January 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Utvärdera av MgSO4 som bolusdos - fastställa så att önskad peak-koncentration av Magnesium nås i moderns blod samt utvärdera nivån av
Magnesium hos barnet. Dessutom notera eventuella biverkningar hos mor och därmed övervakningsbehov inför framtiden och eventuella biverkningar hos barnet.

Maternal and fetal serum concentrations of magnesium ande maternal surveillance after administration of a 6 g bolus dose of
magnesium sulfate (MgSO4) to women with imminent preterm delivery

Protection of trial subjects:

The study is performed in accordance with the directions from the Swedish Medical Agency and the Ethics committee. Monitoring has been made accordingly, by an independent monitor.

Background therapy:

Magnesium Sulfate 50%w/v Solution for Injection 6g bolus dose given once, may be repeated once after 24 hours.

Evidence for comparator:

N/A

Actual start date of recruitment	02 November 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Sweden: 22
Worldwide total number of subjects	22
EEA total number of subjects	22

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0

Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	22
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Sahlgrenska University Hospital Östra, special delivery ward 314, period: 181102-191120.
No serious adverse advent: 1
Consent withdrawn by subject: 1

Pre-assignment

Screening details:

No serious adverse advent: 1
Consent withdrawn by subject: 1

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	MgSO4

Arm description:

Magnesium Sulfate 50%w/v Solution for Injection 6g bolus dose during 20-30 minutes

Arm type	Active comparator
Investigational medicinal product name	Magnesium Sulfate Heptahydrate 5g/ 10ml 2.5g/ 5ml 1g/ 2ml
Investigational medicinal product code	ATC code: A12CC 02.
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use, Intravenous bolus use

Dosage and administration details:

6 g iv slowly during 20-30 minutes

Number of subjects in period 1	MgSO4
Started	22
Completed	22

Baseline characteristics

Reporting groups

Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	22	22	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Adults (18-64 years)	22	22	
Gender categorical Units: Subjects			
Female	22	22	
Male	0	0	

Subject analysis sets

Subject analysis set title	Decision for end of trial
Subject analysis set type	Full analysis

Subject analysis set description:

The trial was ended after 22 women and fetuses were given treatment. The distribution of data showed that no further recruitment would change that data in such way that any critical /serious high level of magnesium concentration would be reached.

Reporting group values	Decision for end of trial		
Number of subjects	22		
Age categorical Units: Subjects			
In utero	22		
Preterm newborn infants (gestational age < 37 wks)	22		
Adults (18-64 years)	22		
Gender categorical Units: Subjects			
Female	22		
Male	0		

End points

End points reporting groups

Reporting group title	MgSO4

Reporting group description:

Magnesium Sulfate 50%w/v Solution for Injection 6g bolus dose during 20-30 minutes

Subject analysis set title	Decision for end of trial
Subject analysis set type	Full analysis

Subject analysis set description:

The trial was ended after 22 women and fetuses were given treatment. The distribution of data showed that no further recruitment would change that data in such way that any critical /serious high level of magnesium concentration would be reached.

Primary: magnesium concentration levels

End point title	magnesium concentration levels

End point description:

The trial was ended after 22 women and fetuses were given treatment. The distribution of data showed that no further recruitment would change that data in such way that any critical /serious high level of magnesium concentration would be reached.

End point type	Primary

End point timeframe:

2019-dec-29-2020-jan-29

End point values	MgSO4	Decision for end of trial		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	21	21		
Units: mmol/l				
arithmetic mean (standard deviation)	2.19 (± 0.43)	1.03 (± 0.09)		

Statistical analyses

Statistical analysis title	Descriptive

Statistical analysis description:

Data analysis was done using the GraphPad Prism 8 version 8.1.1. T-test, Mann-Whitney test and simple linear regression analysis were applied as appropriate. Pearson’s test was used for normal distribution analysis. A two tailed p-value <0.05 was considered statistically significant. Add Spearmen rank or linear regression

Comparison groups	MgSO4 v Decision for end of trial

Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	other[1]
P-value	≤ 0.05
Method	Wilcoxon (Mann-Whitney)

Notes:

[1] - Data analysis was done using the GraphPad Prism 8 version 8.1.1. T-test, Mann-Whitney test and simple linear regression analysis were applied as appropriate. Pearson’s test was used for normal distribution analysis. A two tailed p-value <0.05 was considered statistically significant. Add Spearmen rank or linear regression

Adverse events

Adverse events information

Timeframe for reporting adverse events:

181102-201229

Adverse event reporting additional description:

1 non-serious adverse events. I person was briefly (<5 minutes) hard do to contact/communicate with during infusion. Blood pressure and pulse as well as saturation was stable, magnesium concentrations was within normal range for the mother; CTG was normal, no cramps occurred. The event was judged as not dependent upon the medication.

Assessment type	Systematic

Dictionary used

Dictionary name	SNOMED CT
Dictionary version	1

Reporting groups

Reporting group title	MgSO4

Reporting group description:

Magnesium Sulfate 50%w/v Solution for Injection 6g bolus dose during 20-30 minutes

Serious adverse events	MgSO4		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 22 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0.05 %

Non-serious adverse events	MgSO4		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 22 (4.55%)		
Social circumstances			
hard to communicate	Additional description: One person was hard to talk to/communicate a few minutes during infusion. All vital parameters for both mother and child was normal as well as serum concentrations for magnesium and the event was judged to be not connected to the infusion.		
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported