



## Clinical trial results:

### Tacrolimus vs prednisolone for the treatment of nephrotic syndrome secondary to minimal change disease: A Randomised Control Trial

#### Summary

EudraCT number	2009-014292-52
Trial protocol	GB
Global end of trial date	11 October 2019

#### Results information

Result version number	v1 (current)
This version publication date	17 December 2020
First version publication date	17 December 2020

#### Trial information

##### Trial identification

Sponsor protocol code	GRIM1002
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00982072
WHO universal trial number (UTN)	-

Notes:

#### Sponsors

Sponsor organisation name	Imperial College Healthcare NHS Trust
Sponsor organisation address	du cane rd London, london, United Kingdom, W12 0HS
Public contact	Prof Megan Griffith, Prof Megan Griffith, +44 2033835272, m.e.griffith@imperial.ac.uk
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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	01 January 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 October 2019
Global end of trial reached?	Yes
Global end of trial date	11 October 2019
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

To compare the effectiveness of tacrolimus versus prednisolone for the treatment of nephrotic syndrome ((hypoalbuminaemia and urine protein/creatinine ratio (PCR) > 100units)) secondary to minimal change disease. The effectiveness of each treatment will be compared by the initial response rate (the proportion of patients achieving complete remission from nephrotic syndrome).

Protection of trial subjects:

na

Background therapy:

nil

Evidence for comparator:

nil

Actual start date of recruitment	01 December 2009
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	United Kingdom: 50
Worldwide total number of subjects	50
EEA total number of subjects	50

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)	50
From 65 to 84 years	0

85 years and over	0
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## Subject disposition

### Recruitment

Recruitment details:

52 patients

### Pre-assignment

Screening details:

minimal change disease

### Period 1

Period 1 title	overall study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

### Arms

Are arms mutually exclusive?	Yes
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<b>Arm title</b>	prednisolone
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Arm description:

prednisolone

Arm type	Active comparator
Investigational medicinal product name	prednisolone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

1mg/kg/day

<b>Arm title</b>	tacrolimus
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Arm description:

tacrolimus

Arm type	Experimental
Investigational medicinal product name	tacrolimus
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

0.05mg/kg bd

Number of subjects in period 1	prednisolone	tacrolimus
Started	25	25
Completed	25	25



## Baseline characteristics

### Reporting groups

Reporting group title	overall study
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Reporting group description: -

Reporting group values	overall study	Total	
Number of subjects	50	50	
Age categorical			
age			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	50	50	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	23	23	
Male	27	27	

## End points

### End points reporting groups

Reporting group title	prednisolone
Reporting group description: prednisolone	
Reporting group title	tacrolimus
Reporting group description: tacrolimus	

### Primary: number of patients achieving complete remission of nephrotic syndrome at 8 weeks

End point title	number of patients achieving complete remission of nephrotic syndrome at 8 weeks <sup>[1]</sup>
End point description: number of patients achieving complete remission of nephrotic syndrome at 8 weeks	
End point type	Primary
End point timeframe: 8 weeks	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: as in published paper

End point values	prednisolone	tacrolimus		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	25	25		
Units: patients	21	17		

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information<sup>[1]</sup>

Timeframe for reporting adverse events:  
throughout trial. 2009-2019

Assessment type	Non-systematic
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### Dictionary used

Dictionary name	MedDRA
Dictionary version	10

### Reporting groups

Reporting group title	prednisolone
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Reporting group description:  
prednisolone

Reporting group title	tacrolimus
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Reporting group description:  
tacrolimus

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: The number of non serious adverse events is reported in the paper.

Serious adverse events	prednisolone	tacrolimus	
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 25 (16.00%)	3 / 25 (12.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Cardiac disorders			
hypertension			
subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Headache	Additional description: Headache		
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Diverticular perforation	Additional description: as above		
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			

subjects affected / exposed	0 / 25 (0.00%)	1 / 25 (4.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Respiratory tract infection			
subjects affected / exposed	1 / 25 (4.00%)	1 / 25 (4.00%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Fracture radius	Additional description: Fracture radius		
subjects affected / exposed	1 / 25 (4.00%)	0 / 25 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

<b>Non-serious adverse events</b>	prednisolone	tacrolimus	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 25 (0.00%)	0 / 25 (0.00%)	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Age range was 18-74
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Notes:

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### Online references

<http://www.ncbi.nlm.nih.gov/pubmed/31953303>