



## Clinical trial results:

**Ensayo clínico aleatorizado, doble ciego con propionato de fluticasona tópico 2 veces por semana, como tratamiento de mantenimiento, para reducir el riesgo de recidivas de dermatitis atópica leve o moderada en niño.**

**Randomised controlled, double blind trial of topical twice weekly fluticasone propionate maintenance treatment to reduce risk of relapse in mild or moderate atopic dermatitis in children.**

## Summary

EudraCT number	2008-005360-14
Trial protocol	ES
Global end of trial date	27 April 2012

## Results information

Result version number	v1 (current)
This version publication date	21 October 2022
First version publication date	21 October 2022
Summary attachment (see zip file)	Medical jurnal article Rubio-Gomis et al (Rubio-Gomis E. Allergologia et Immunopathologia 2018.pdf)

## Trial information

### Trial identification

Sponsor protocol code	FLUTIDANENES08
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### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01772056
WHO universal trial number (UTN)	-
Other trial identifiers	ISCI. Ministerio de Ciencia e Innovación: EC08/00004

Notes:

## Sponsors

Sponsor organisation name	Instituto de Salud Carlos III
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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	14 May 2012
Is this the analysis of the primary completion data?	Yes
Primary completion date	23 March 2012
Global end of trial reached?	Yes
Global end of trial date	27 April 2012
Was the trial ended prematurely?	Yes

Notes:

### General information about the trial

Main objective of the trial:

El objetivo principal de este estudio es probar la eficacia de Fluticasona propionato al 0.05% en crema frente placebo (vehículo de la crema) aplicada en las zonas de lesión 2 veces por semana hasta la recidiva o un máximo de 16 semanas para disminuir las recidivas de DA en niños de 2 a 10 años.

Protection of trial subjects:

No specific measures .

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 January 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

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## Population of trial subjects

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### Subjects enrolled per country

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Country: Number of subjects enrolled	Spain: 61
Worldwide total number of subjects	61
EEA total number of subjects	61

Notes:

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### Subjects enrolled per age group

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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)	61
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

A total of 61 patients were assessed for eligibility, of these children, seven had failed screening (1 No informed consent; 6 Inclusion/exclusion criteria not met).

### Pre-assignment period milestones

Number of subjects started	61
Number of subjects completed	54

### Pre-assignment subject non-completion reasons

Reason: Number of subjects	No informed consent: 1
Reason: Number of subjects	Inclusion/exclusion criteria not met: 6

### Period 1

Period 1 title	Open-label Stabi-lization Phase (OSP)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

### Arms

<b>Arm title</b>	Open-label Stabi-lization Phase (OSP)
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Arm description:

Children were enrolled into an initial OSP on treatment with twice daily Fluticasone Propionate cream 0.05% up to 2 weeks. Those children who achieved treatment success in OSP entered the DMP.

Arm type	Treatment success
Investigational medicinal product name	Fluticasone propionate
Investigational medicinal product code	PR1
Other name	
Pharmaceutical forms	Cream
Routes of administration	Cutaneous use

Dosage and administration details:

Fluticasone propionate cream 0.05% twice daily up to 2 weeks.

<b>Number of subjects in period 1<sup>[1]</sup></b>	Open-label Stabi-lization Phase (OSP)
Started	54
Completed	49
Not completed	5
Adverse event, non-fatal	1
Lack of efficacy	3
Protocol deviation	1

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: A total of 61 patients were assessed for eligibility, of these children, seven had failed screening. Hence, fifty-four patients entered the OSP, of them 49 continued into the DMP and were randomized (twenty six were in the FP group).

## Period 2

Period 2 title	Double-blind Maintenance Phase (DMP).
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Monitor, Data analyst, Carer, Assessor, Subject

Blinding implementation details:

Randomization was generated by a random number table; the list was produced by the statistical service of the CRO. A blinded copy and clinical trial coded medication were received and stored by the clinical trials pharmacist at Consorcio Hospital General Universitario de Valencia (CHGUV). The pharmacist dispensed the research drugs packs according with the research assistants that used consecutively numbered packs to allocate new participants to treatment groups.

## Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Fluticasone propionate treatment

Arm description:

To receive Fluticasone propionate twice weekly on consecutive days for 16 weeks or at relapse, in which case they were withdrawn from the study.

Arm type	Experimental
Investigational medicinal product name	Fluticasone propionate
Investigational medicinal product code	PR1
Other name	
Pharmaceutical forms	Cream
Routes of administration	Cutaneous use

Dosage and administration details:

Fluticasone propionate cream 0.05% twice weekly on consecutive days

<b>Arm title</b>	Vehicle treatment
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Arm description:

To receive vehicle (PFCO/W Base®- Guinama S.L.U., Propyleneglycol and Aqua conservans) twice weekly on consecutive days for 16 weeks or at relapse.

Arm type	Placebo
Investigational medicinal product name	Vehicle
Investigational medicinal product code	PL1
Other name	PFCO/W Base®- Guinama S.L.U., Propyleneglycol and Aqua conservans.
Pharmaceutical forms	Cream
Routes of administration	Cutaneous use

Dosage and administration details:

PFCO/W Base®- Guinama S.L.U., Propyleneglycol and Aqua conservans, twice weekly on consecutive days.

Number of subjects in period 2	Fluticasone propionate treatment	Vehicle treatment
Started	26	23
Completed	24	21
Not completed	2	2
Consent withdrawn by subject	-	1
Protocol deviation	2	1

## Baseline characteristics

### Reporting groups

Reporting group title	Open-label Stabi-lization Phase (OSP)
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Reporting group description: -

Reporting group values	Open-label Stabi-lization Phase (OSP)	Total	
Number of subjects	54	54	
Age categorical Units: Subjects			
Children (2-11 years)	54	54	
Gender categorical Units: Subjects			
Female	29	29	
Male	25	25	

## End points

### End points reporting groups

Reporting group title	Open-label Stabi-lization Phase (OSP)
Reporting group description: Children were enrolled into an initial OSP on treatment with twice daily Fluticasone Propionate cream 0.05% up to 2 weeks. Those children who achieved treatment success in OSP entered the DMP.	
Reporting group title	Fluticasone propionate treatment
Reporting group description: To receive Fluticasone propionate twice weekly on consecutive days for 16 weeks or at relapse, in which case they were withdrawn from the study.	
Reporting group title	Vehicle treatment
Reporting group description: To receive vehicle (PFCO/W Base®- Guinama S.L.U., Propyleneglycol and Aqua conservans) twice weekly on consecutive days for 16 weeks or at relapse.	

### Primary: Relapse of Atopic Dermatitis

End point title	Relapse of Atopic Dermatitis
End point description: The primary study endpoint was a relapse rate of Atopic Dermatitis, defined as an SCORAD >5 or ≥25% initial SCORAD.	
End point type	Primary
End point timeframe: 16 weeks	

End point values	Fluticasone propionate treatment	Vehicle treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	23		
Units: si/no	7	13		

### Statistical analyses

Statistical analysis title	Log Rank
Statistical analysis description: Differences between treatment groups were tested using Log Rank (Mantel-Cox).	
Comparison groups	Fluticasone propionate treatment v Vehicle treatment
Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.05
Method	Logrank





## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Total study period (2 weeks + 16 weeks)

Adverse event reporting additional description:

Safety was assessed by monitoring adverse events. Causal relationship of the clinical event to the use of the medication studied was assessed by clinical researchers. The adverse cutaneous reactions related with corticosteroid treatment were particularly considered (skin atrophy, telangiectasia, striae and hypertrichosis).

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	2.0
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### Reporting groups

Reporting group title	Open-label Stabi-lization Phase (OSP)
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Reporting group description: -

Reporting group title	fluticasone propionate (FP)
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Reporting group description: -

Reporting group title	Vehicle group
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Reporting group description: -

Serious adverse events	Open-label Stabi-lization Phase (OSP)	fluticasone propionate (FP)	Vehicle group
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 54 (0.00%)	1 / 26 (3.85%)	1 / 23 (4.35%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Infections and infestations			
Mastoiditis			
subjects affected / exposed	0 / 54 (0.00%)	1 / 26 (3.85%)	1 / 23 (4.35%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis	Additional description: Aphthous stomatitis		
subjects affected / exposed	0 / 54 (0.00%)	1 / 26 (3.85%)	0 / 23 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

<b>Non-serious adverse events</b>	Open-label Stabi- lization Phase (OSP)	fluticasone propionate (FP)	Vehicle group
Total subjects affected by non-serious adverse events subjects affected / exposed	1 / 54 (1.85%)	8 / 26 (30.77%)	10 / 23 (43.48%)
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0	2 / 26 (7.69%) 2	0 / 23 (0.00%) 0
Skin and subcutaneous tissue disorders Wound subjects affected / exposed occurrences (all)  Skin abrasion subjects affected / exposed occurrences (all)  Eczema subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0  0 / 54 (0.00%) 0  1 / 54 (1.85%) 1	2 / 26 (7.69%) 2  2 / 26 (7.69%) 2  0 / 26 (0.00%) 0	0 / 23 (0.00%) 0  0 / 23 (0.00%) 0  1 / 23 (4.35%) 1
Infections and infestations Respiratory tract infection subjects affected / exposed occurrences (all)  Tonsillitis subjects affected / exposed occurrences (all)  Otitis media subjects affected / exposed occurrences (all)	0 / 54 (0.00%) 0  0 / 54 (0.00%) 0  0 / 54 (0.00%) 0	4 / 26 (15.38%) 4  3 / 26 (11.54%) 3  0 / 26 (0.00%) 0	3 / 23 (13.04%) 3  2 / 23 (8.70%) 2  4 / 23 (17.39%) 4

## 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.

It was prematurely terminated because patient recruitment was very slow and the economic grant had ended, nonetheless the number of recruited patients was enough according to the estimated sample size, so this study can be conclusive with certainty.
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Notes: