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

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Instituto de Salud Carlos III
Sponsor organisation address	C/ Sinesio Delgado, 4, Madrid, Spain, 28029
Public contact	Instituto de Salud Carlos III, Instituto de Salud Carlos III (ISCIII), +34 91 822 24 51, comunicacion@isciii.es
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Sponsor organisation name	Consorcio Hospital General Universitario de Valencia
Sponsor organisation address	Avda Tres Cruces nº2, Valencia, Spain, 46014
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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:

Population of trial subjects

Subjects enrolled per country

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

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)	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, ofthese children, seven had failed screening (1 No informed consent; 6 Inclusion/exclusion criterianot 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

Arm title	Open-label Stabi-lization Phase (OSP)

Arm description:

Children were enrolled into an initial OSP on treatment with twice daily Fruticasone 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.

Number of subjects in period 1[1]	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 blindedcopy and clinical trial coded medication were received andstored by the clinical trials pharmacist at Consorcio HospitalGeneral Universitario de Valencia (CHGUV). The pharma-cist dispensed the research drugs packs according with theresearch assistants that used consecutively numbered packsto allocate new participants to treatment groups.

Arms

Are arms mutually exclusive?	Yes
Arm title	Fluticasone propionate treatmen

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

Arm title	Vehicle treatment

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 treatmen	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)

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 Fruticasone Propionate cream 0.05% up to 2 weeks. Those children who achieved treatment success in OSP entered the DMP.	
Reporting group title	Fluticasone propionate treatmen
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 treatmen	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:	
Differ-ences between treatment groups were tested using Log Rank (Mantel-Cox).	
Comparison groups	Fluticasone propionate treatmen 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

Dictionary used

Dictionary name	MedDRA
Dictionary version	2.0

Reporting groups

Reporting group title	Open-label Stabi-lization Phase (OSP)
Reporting group description: -	
Reporting group title	fluticasone propionate (FP)
Reporting group description: -	
Reporting group title	Vehicle group

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 %

Non-serious adverse events	Open-label Stabilization 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	0 / 54 (0.00%)	2 / 26 (7.69%)	0 / 23 (0.00%)
occurrences (all)	0	2	0
Skin and subcutaneous tissue disorders			
Wound			
subjects affected / exposed	0 / 54 (0.00%)	2 / 26 (7.69%)	0 / 23 (0.00%)
occurrences (all)	0	2	0
Skin abrasion			
subjects affected / exposed	0 / 54 (0.00%)	2 / 26 (7.69%)	0 / 23 (0.00%)
occurrences (all)	0	2	0
Eczema			
subjects affected / exposed	1 / 54 (1.85%)	0 / 26 (0.00%)	1 / 23 (4.35%)
occurrences (all)	1	0	1
Infections and infestations			
Respiratory tract infection			
subjects affected / exposed	0 / 54 (0.00%)	4 / 26 (15.38%)	3 / 23 (13.04%)
occurrences (all)	0	4	3
Tonsillitis			
subjects affected / exposed	0 / 54 (0.00%)	3 / 26 (11.54%)	2 / 23 (8.70%)
occurrences (all)	0	3	2
Otitis media			
subjects affected / exposed	0 / 54 (0.00%)	0 / 26 (0.00%)	4 / 23 (17.39%)
occurrences (all)	0	0	4

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

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.

Notes: