Clinical trial results:
A designed Patient-centered Intervention to Improve medical Adherence in Topical Treatment of psoriasis - A Study protocol

Summary

EudraCT number	2016-002143-42
Trial protocol	DK
Global end of trial date	29 August 2017

Results information

Result version number	v1 (current)
This version publication date	23 December 2017
First version publication date	23 December 2017

Trial information

Trial identification

Sponsor protocol code	16013

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02858713
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Odense University Hospital
Sponsor organisation address	Kløvervænget 15, Odense, Denmark, 5000
Public contact	Mathias Tiedemann Svendsen, Odense University Hospital, +45 65413239, mathias.tiedemann.svendsen@rsyd.dk
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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	21 November 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 August 2017
Global end of trial reached?	Yes
Global end of trial date	29 August 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Test if an app for smartphones can improve Medical adherence in psoriasis patients

Protection of trial subjects:

Assessment of adverse events at all study visits.

Background therapy:

Treatment with calcipqotriol/betamethasone dipropionate cutaneous foam.

Evidence for comparator: -

Actual start date of recruitment	09 January 2017
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	Denmark: 134
Worldwide total number of subjects	134
EEA total number of subjects	134

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)	106
From 65 to 84 years	28
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were recruited at the dermatology outpatient clinic at Odense University Hospital and by advertisement in local news media.
Patients were included in the period 9 January 2017 to 29 February 2017.

Pre-assignment

Screening details:

Inclusion criteria: Patients (legally competent patients aged between 18-75 years) who owned a smartphone or had skills for use of a smartphone who were diagnosed with mild-to-moderate psoriasis, and who were candidates for treatment with calcipotriol/betamethasone dipropionate cutaneous foam.

Period 1

Period 1 title	Intervention (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Non-intervention

Arm description:

Patients received topical Cal/BD cutaneous foam. The foam was prescribed for once daily application in a 28-day treatment period.

Arm type	Active comparator
Investigational medicinal product name	enstilar
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous foam
Routes of administration	Cutaneous use

Dosage and administration details:

Once daily cutaneous application

Arm title	Intervention

Arm description:

Patients received topical Cal/BD cutaneous foam. The foam was prescribed for once daily application in a 28-day treatment period. In addition, the patients received a 28-day supporting app, which provided once-daily compulsory treatment reminders and daily information on number of treatment applications and applied amount of prescribed Cal/BD cutaneous foam. The information was obtained by the chip in the electronic monitor synchronizing via Bluetooth® to the app.

Arm type	Experimental
Investigational medicinal product name	enstilar
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cutaneous foam
Routes of administration	Cutaneous use

Dosage and administration details:

Once daily cutaneous application

Number of subjects in period 1	Non-intervention	Intervention
Started	66	68
Completed	61	61
Not completed	5	7
Adverse event, non-fatal	-	1
Pregnancy	1	1
Lost to follow-up	4	5

Baseline characteristics

Reporting groups	
Reporting group title	Intervention (overall period)

Reporting group description: -

Reporting group values	Intervention (overall period)	Total	
Number of subjects	134	134	
Age categorical 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)	106	106	
From 65-84 years	28	28	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	52	52	
Male	82	82	

End points

End points reporting groups

Reporting group title	Non-intervention

Reporting group description:

Patients received topical Cal/BD cutaneous foam. The foam was prescribed for once daily application in a 28-day treatment period.

Reporting group title	Intervention

Reporting group description:

Patients received topical Cal/BD cutaneous foam. The foam was prescribed for once daily application in a 28-day treatment period. In addition, the patients received a 28-day supporting app, which provided once-daily compulsory treatment reminders and daily information on number of treatment applications and applied amount of prescribed Cal/BD cutaneous foam. The information was obtained by the chip in the electronic monitor synchronizing via Bluetooth® to the app.

Primary: rate of secondary medical adherence

End point title	rate of secondary medical adherence

End point description:

End point type	Primary

End point timeframe:

Week 4

End point values	Non-intervention	Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	61	59		
Units: %	38	65		

Statistical analyses

Statistical analysis title	Rate of adherent patients

Statistical analysis description:

we dichotomized adherence rates obtained by Electronic monitor with a selected cut-off of 80%, with adherence rates above 80% considered adherent

Comparison groups	Non-intervention v Intervention
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Regression, Linear
Parameter estimate	Odds ratio (OR)
Point estimate	2.994

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.42
upper limit	6.28

Secondary: LS-PGA: Change baseline to week 4

End point title	LS-PGA: Change baseline to week 4
End point description:	
End point type	Secondary
End point timeframe:	
Week 4	

End point values	Non-intervention	Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	65	65		
Units: LS-PGA				
arithmetic mean (confidence interval 95%)	1.46 (1.17 to 1.75)	1.86 (1.59 to 2.13)		

Statistical analyses

Statistical analysis title	LS-PGA: Chanmge baseline to week 4
Comparison groups	Non-intervention v Intervention
Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.047
Method	Regression, Linear
Parameter estimate	Coefficient
Point estimate	0.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.005
upper limit	0.795

Secondary: LS-PGA: Change baseline week 8

End point title	LS-PGA: Change baseline week 8

End point description:

End point type	Secondary

End point timeframe:

Week 8

End point values	Non-intervention	Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	63	64		
Units: LS-PGA				
arithmetic mean (confidence interval 95%)	2.16 (1.86 to 2.46)	2.25 (1.96 to 2.54)		

Statistical analyses

Statistical analysis title	LS-PGA: Change baseline to week 8
Comparison groups	Non-intervention v Intervention
Number of subjects included in analysis	127
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.662
Method	Regression, Linear
Parameter estimate	Coefficient
Point estimate	0.091
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.321
upper limit	0.504

Secondary: LS-PGA: Change baseline to week 26

End point title	LS-PGA: Change baseline to week 26

End point description:

End point type	Secondary

End point timeframe:

Week 26

End point values	Non-intervention	Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	61	61		
Units: LS-PGA				
arithmetic mean (confidence interval 95%)	1.80 (1.49 to 2.11)	1.98 (1.66 to 2.31)		

Statistical analyses

Statistical analysis title	LS-PGA: Change baseline to week 26
Comparison groups	Non-intervention v Intervention
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.424
Method	Regression, Linear
Parameter estimate	Coefficient
Point estimate	0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.264
upper limit	0.625

Secondary: DLQI: Change baseline to week 4

End point title	DLQI: Change baseline to week 4

End point description:

End point type	Secondary

End point timeframe:

Week 4

End point values	Non-intervention	Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	65	65		
Units: DLQI				
arithmetic mean (confidence interval 95%)	4.54 (3.47 to 5.61)	4.12 (3.27 to 4.98)		

Statistical analyses

Statistical analysis title	LS-PGA: Change baseline to week 4
Comparison groups	Intervention v Non-intervention
Number of subjects included in analysis	130
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.545
Method	Regression, Linear
Parameter estimate	Coefficient
Point estimate	-0.415
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.77
upper limit	0.939

Secondary: DLQI: Change baseline to week 8	
End point title	DLQI: Change baseline to week 8
End point description:	
End point type	Secondary
End point timeframe:	
Week 8	

End point values	Non-intervention	Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	63	64		
Units: DLQI				
arithmetic mean (confidence interval 95%)	5.17 (3.92 to 6.43)	4.59 (3.71 to 5.48)		

Statistical analyses

Statistical analysis title	DLQI: Change baseline to week 8
Comparison groups	Non-intervention v Intervention
Number of subjects included in analysis	127
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.45
Method	Regression, Linear
Parameter estimate	Coefficient
Point estimate	-0.581

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.099
upper limit	0.938

Secondary: DLQI: Change baseline to week 26

End point title	DLQI: Change baseline to week 26
End point description:	

End point type	Secondary
End point timeframe:	
Week 26	

End point values	Non-intervention	Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	61	61		
Units: DLQI				
arithmetic mean (confidence interval 95%)	5.00 (3.69 to 6.31)	4.23 (3.25 to 5.21)		

Statistical analyses

Statistical analysis title	DLQI: Change baseline to week 26
Comparison groups	Intervention v Non-intervention
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.348
Method	Regression, Linear
Parameter estimate	Coefficient
Point estimate	-0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.389
upper limit	0.848

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Baseline, week 4, 8 and 26.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	19

Reporting groups	
Reporting group title	ADVERSE EVENTS

Reporting group description: -

Serious adverse events	ADVERSE EVENTS		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 134 (0.75%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Musculoskeletal and connective tissue disorders			
Infection in knee prothesis			
subjects affected / exposed	1 / 134 (0.75%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	ADVERSE EVENTS		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	42 / 134 (31.34%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Relapse of carcinoma in situ of the glottis	Additional description: Relapse of carcinoma in situ of the glottis (not related to enstilar cutaneous foam treatment)		
subjects affected / exposed	1 / 134 (0.75%)		
occurrences (all)	1		
Vascular disorders			
Fainting	Additional description: Fainting (not related to enstilar cutaneous foam treatment)		

subjects affected / exposed	1 / 134 (0.75%)		
occurrences (all)	1		
Ear and labyrinth disorders			
Nausea	Additional description: Nausea after accidentally inhaling gas from the Enstilar cutaneous faom canister		
subjects affected / exposed	3 / 134 (2.24%)		
occurrences (all)	3		
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease	Additional description: Sensation worsening of Chronic obstructive pulmonary disease when accidentally inhaled gas from the Enstilar Cutaneous foam canister.		
subjects affected / exposed	1 / 134 (0.75%)		
occurrences (all)	1		
Hepatobiliary disorders			
Elevated liver enzymes	Additional description: Elevated liver enzymes (not related to enstilar cutaneous foam treatment)		
subjects affected / exposed	3 / 134 (2.24%)		
occurrences (all)	3		
Skin and subcutaneous tissue disorders			
various cutaneous manifestations	Additional description: 11 different skin manifestations (none related to Enstilar cutaneous foam treatment)		
subjects affected / exposed	16 / 134 (11.94%)		
occurrences (all)	16		
Renal and urinary disorders			
Elevated creatinin levels	Additional description: Elevated creatinin levels (not related to enstilar cutaneous foam treatment)		
subjects affected / exposed	1 / 134 (0.75%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Various musculoskeletal disorder	Additional description: Various musculousskeletal disorder (not related to enstilar cutaneous foam treatment)		
subjects affected / exposed	8 / 134 (5.97%)		
occurrences (all)	8		
Infections and infestations			
Lung and skin infection	Additional description: Lung and skin infection (not related to enstilar cutaneous foam treatment)		
subjects affected / exposed	8 / 134 (5.97%)		
occurrences (all)	8		

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