EU Clinical Trials Register

Clinical trial results:
Pilot Study: Evaluating the effect of 300microgram testosterone patches in addition to Hormone Replacement Therapy on arterial compliance, insulin resistance and sexual desire

Summary

EudraCT number	2009-013275-21
Trial protocol	GB
Global end of trial date	07 February 2012

Results information

Result version number	v1 (current)
This version publication date	18 December 2019
First version publication date	18 December 2019

Trial information

Trial identification

Sponsor protocol code	05-2009

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01208038
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Imperial College London
Sponsor organisation address	South Kensington Campus, London, United Kingdom, SW7 2AZ
Public contact	Nick Panay, Imperial College London, +44 0208 383 1111, n.panay@imperial.ac.uk
Scientific contact	Nick Panay, Imperial College London, +44 0208 383 1111, n.panay@imperial.ac.uk

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	05 February 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 February 2012
Global end of trial reached?	Yes
Global end of trial date	07 February 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The principle purpose of this study is to examine the effects of the testosterone patch, in conjuction with HRT, on the arterial walls and on the sensitivity to insulin in postmenopausal women.

Protection of trial subjects:

None

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 March 2011
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	United Kingdom: 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:

Participants were recruited between March 2011 and February 2012

Pre-assignment

Screening details:

The investigators aimed to recruit 20 postmenopausal women to wear the testosterone patch for 3 months, finally managed recruit 22 participants, 1 patient withdrew before commencing study drug

Period 1

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

Arms

Arm title	Intrinsa Transdermal testosterone patch

Arm description:

Participants received Intrinsa Transdermal testosterone patch

Arm type	Experimental
Investigational medicinal product name	Intrinsa Transdermal testosterone patch
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Transdermal patch
Routes of administration	Transdermal use

Dosage and administration details:

300 microgram transdermal testosterone patch, applied twice weekly for 12 weeks

Number of subjects in period 1[1]	Intrinsa Transdermal testosterone patch
Started	21
Completed	21

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: 1 participant withdrew before the treatment

Baseline characteristics

Reporting groups

Reporting group title	Overall period

Reporting group description: -

Reporting group values	Overall period	Total	
Number of subjects	21	21	
Age categorical			
Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous			
Units: years			
geometric mean	53		
standard deviation	± 6.7	-	
Gender categorical			
Units: Subjects			
Female	21	21	
Male	0	0	
Augmentation Index			
Peripheral pressure waveforms were captured using radial artery application tonometry via the SphygmoCor apparatus (software version 8.0). The central pressure waveform was then derived from an averaged peripheral waveform using a validated, transfer function . The augmentation index (AIx), which gives a composite measure of wave reflection and systemic arterial stiffness can be calculated by analysis of the central waveform. Aix was defined as the difference between the first and second systolic peaks of the central pressure waveform, expressed as a percentage of the cent			
Units: percentage of Arterial stiffness			
geometric mean	24.21		
standard deviation	± 10.70	-	
Reactive Hyperaemia Index			
Reactive Hyperaemia Index (RHI) was calculated automatically by the EndoPAT 2000 computer algorithm from the ratio of pulse wave amplitude before and after ischemia, compared to the control arm. Official reference values do not exist however a lower RHI (<2.0) is usually considered indicative of endothelial dysfunction.			
Units: Unit on the scale			
geometric mean	1.79		
standard deviation	± 0.36	-	
Brief Profile of Female Sexual Function (B-PFSF)			
Blood samples were taken for fasting glucose and insulin levels. From these results, insulin resistance was then estimated using the updated homeostasis model assessment method for insulin resistance (HOMA-IR) computer algorithm. A higher HOMA-IR indicates a higher degree of insulin resistance. Typically a cutoff of HOMA-IR for identifying those with insulin resistance is 2.5.			

Units: Unit on the scale			
geometric mean	15.3		
standard deviation	± 9.1	-	

Homeostatic Model Assessment of Insulin Resistance (HOMA-IR)			

Libido was assessed at each visit using the Brief profile of female sexual function (BPFSF), a validated self-administered questionnaire for identifying Hypoactive Sexual Desire Disorder (HSDD). The BPFSF is based on 7 questions. Each question is scored on a 6-point scale from 'always' to 'never'. A total score is calculated from the sum of all questions. Previous studies have identified a score of less than 20 as suggestive of HSDD.

Units: Unit on the scale			
geometric mean	0.78		
standard deviation	± 0.40	-	

End points

End points reporting groups

Reporting group title	Intrinsa Transdermal testosterone patch
Reporting group description:	
Participants received Intrinsa Transdermal testosterone patch	

Primary: Arterial Compliance - Augmentation Index

End point title	Arterial Compliance - Augmentation Index[1]

End point description:

Peripheral pressure waveforms were captured using radial artery application tonometry via the SphygmoCor apparatus (AtCor Medical Ltd., Sydney, Australia; software version 8.0). The central (ascending aortic) pressure waveform was then derived from an averaged peripheral waveform using a validated, transfer function. The augmentation index (AIx), which gives a composite measure of wave reflection and systemic arterial stiffness can then be calculated by analysis of the central waveform. Aix was defined as the difference between the first and second systolic peaks of the central pressure waveform, expressed as a percentage of the central pulse pressure.

End point type	Primary

End point timeframe:

12 weeks from baseline

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: A pilot study no statistical analyses.

End point values	Intrinsa Transdermal testosterone patch			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: percentage of Arterial stiffness				
geometric mean (confidence interval 95%)	1.067 (-3.85 to 1.72)			

Statistical analyses

No statistical analyses for this end point

Primary: Endothelial function

End point title	Endothelial function[2]

End point description:

Reactive Hyperaemia Index (RHI) was calculated automatically by the EndoPAT 2000 computer algorithm from the ratio of pulse wave amplitude before and after ischemia, compared to the control arm. Official reference values do not exist however a lower RHI (<2.0) is usually considered indicative of endothelial dysfunction.

End point type	Primary

End point timeframe:

12 weeks from baseline

Notes:

[2] - 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: A pilot study no statistical analyses.

End point values	Intrinsa Transdermal testosterone patch			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: units on a scale				
geometric mean (confidence interval 95%)	0.06 (-0.19 to 0.31)			

Statistical analyses

No statistical analyses for this end point

Secondary: Insulin resistance - HOMA-IR

End point title	Insulin resistance - HOMA-IR

End point description:

Blood samples were taken for fasting glucose and insulin levels. From these results, insulin resistance was then estimated using the updated homeostasis model assessment method for insulin resistance (HOMA-IR) computer algorithm. A higher HOMA-IR indicates a higher degree of insulin resistance. Typically a cutoff of HOMA-IR for identifying those with insulin resistance is 2.5.

End point type	Secondary

End point timeframe:

12 weeks from baseline

End point values	Intrinsa Transdermal testosterone patch			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: units on a scale				
geometric mean (confidence interval 95%)	0.106 (-0.20 to 0.41)			

Statistical analyses

No statistical analyses for this end point

Secondary: Libido - B-PFSF score

End point title	Libido - B-PFSF score

End point description:

Libido was assessed at each visit using the Brief profile of female sexual function (BPFSF), a validated self-administered questionnaire for identifying Hypoactive Sexual Desire Disorder (HSDD). The BPFSF is based on 7 questions. Each question is scored on a 6-point scale from 'always' to 'never'. A total score is calculated from the sum of all questions. Previous studies have identified a score of less than 20 as suggestive of HSDD.

End point type	Secondary

End point timeframe:

12 weeks from baseline

End point values	Intrinsa Transdermal testosterone patch			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: unit on scale				
geometric mean (confidence interval 95%)	5.05 (2.63 to 7.46)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events: 12 weeks	
Assessment type	Systematic

Dictionary used

Dictionary name	SNOMED CT
Dictionary version	10

Reporting groups

Reporting group title	Intrinsa Transdermal testosterone patch
Reporting group description: Participants received Intrinsa Transdermal testosterone patch	

Serious adverse events	Intrinsa Transdermal testosterone patch		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 21 (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 %

Non-serious adverse events	Intrinsa Transdermal testosterone patch		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 21 (33.33%)		
Eye disorders			
Blepharitis			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Reproductive system and breast disorders			
per vagina spotting			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Skin irritation			
subjects affected / exposed	4 / 21 (19.05%)		
occurrences (all)	4		

Acne			
subjects affected / exposed	1 / 21 (4.76%)		
occurrences (all)	1		
Endocrine disorders			
Increased facial hair			
subjects affected / exposed	2 / 21 (9.52%)		
occurrences (all)	2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 February 2011	Remove the exclusion Criteria of having received testosterone implants within the last 12 months or other androgen therapy within the last 3 months (from 6 months in the earlier protocol).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

 None reported