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COMPLETED 

Assessment of Long Term Treatment With Testosterone Undecanoate in Males With Hypogonadism

ClinicalTrials.gov ID  NCT00220298

Sponsor  Bayer

Information provided by  Bayer (Responsible Party)

Last Update Posted  2014-12-30

Table View Tab

Trial Contacts

Contacts

ICMJE

Contact information is only displayed when the study is recruiting subjects

Study Record Dates

First Submitted

ICMJE

2005-09-16

First Posted

ICMJE

Feedback 

2005-09-22

Last Update Posted

2014-12-30

Last Verified

2014-12

Outcome Measures

Change History[See all versions of this study.](#)**Primary (Current)**

ICMJE

(Submitted: 2008-09-25)

- Efficacy and Safety of long term treatment with TU under real-life conditions [Time Frame: Every 3 months during treatment and after final injection]

Primary (Original)

ICMJE

(Submitted: 2005-09-16)

- Efficacy and Safety of long term treatment with TU under real-life conditions

Secondary (Current)

ICMJE

(Submitted: 2008-09-25)

- Assessment of treatment satisfaction by patient [Time Frame: 6,10, and 14 injections]

Secondary (Original)

ICMJE

(Submitted: 2005-09-16)

- Assessment of treatment satisfaction by patient

Other Pre-specified (Current)

Not provided

Other Pre-specified (Original)

Not provided

Trial Description

Brief Title[ICMJE](#)

Assessment of Long Term Treatment With Testosterone Undecanoate in Males With Hypogonadism

Official Title[ICMJE](#)

Open One-arm Study to Investigate Safety and Efficacy of Intramuscular Injections of 1000 mg Testosterone Undecanoate (TU) in Hypogonadal Men at Variable Intervals During a 136-week to 192-week Treatment Including Pharmacokinetics

Brief Summary

This study will evaluate the preparation of testosterone undecanoate under conditions which resemble real-life situations.

Detailed Description

The study has previously been posted by Schering AG, Germany. Schering AG, Germany has been renamed to Bayer Schering Pharma AG, Germany. Bayer Schering Pharma AG, Germany is the sponsor of the trial.

Study Type[ICMJE](#)

Interventional

Study Phase[ICMJE](#)

Phase 3

Study Design[ICMJE](#)

Allocation:

Non-Randomized

Interventional Model:

Single Group Assignment

Masking:

None (Open Label)

Primary Purpose:

Treatment

Condition[ICMJE](#)

- Hypogonadism

Intervention[ICMJE](#)

- Drug: Testosterone undecanoate (TU) - NebidoTM
 - Drug treatment with 14 injections of one ampoule of Nebido (1000 mg of testosterone undecanoate) at individually adjusted injection intervals

Study Arms

ICMJE

- Experimental: Arm 1
 - Interventions:
 - Drug: Testosterone undecanoate (TU) - NebidoTM

Publications *

- Behre HM and Elliesen J. Safety and efficacy of intramuscular injections of 1000 mg testosterone undecanoate: A prospective multicenter study in hypogonadal men under conditions resembling real-life situations. Proceedings of the 22nd Annual European Association of Urology (EAU); 2007 Mar 22; Berlin, Germany. Eur Urol Suppl 2007;6(2):108.

* Includes publications given by the data provider as well as publications identified by ClinicalTrials.gov identifier (NCT Number) in Medline.

Recruitment Information

Recruitment Status

ICMJE

Completed

Enrollment (Actual)

ICMJE

(Submitted: 2014-12-29)

96

Original Enrollment

ICMJE

Not provided

Study Start Date

ICMJE

2003-02

Primary Completion Date (Actual)

2007-10 (Final data collection date for primary outcome measure)

Study Completion Date (Actual)

ICMJE

2007-10

Eligibility Criteria

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Inclusion Criteria:

- Hypogonadal men, aged 18-75 years with low serum total testosterone (TT) levels and symptoms of androgen deficiency

Exclusion Criteria:

- Tumors of the prostate or the male mammary gland including suspicion thereof. Past or present liver tumors or chronic hepatic disease with impairment of liver function, Severe acne.

Sex/Gender

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Sexes Eligible for the Study:
Male

Ages

ICMJE

18 Years to 75 Years (Adult, Older Adult)

Accepts Healthy Volunteers

ICMJE

No

Location Countries

ICMJE

Germany

Removed Location Countries

Administrative Information

NCT Number

ICMJE

NCT00220298

Other Study ID Numbers	ICMJE
91186	
306605(Other Identifier)	
Has Data Monitoring Committee	
No	
U.S. FDA-regulated Product	
Not provided	
IPD Sharing Statement	ICMJE
Not provided	
Current Responsible Party	
Bayer	
Original Responsible Party	
Not provided	
Current Study Sponsor	ICMJE
Bayer	
Original Study Sponsor	ICMJE
Same as current	
Collaborators	ICMJE
Not provided	
Investigators	ICMJE
Study Director: Bayer Study Director Bayer	
PRS Account	
Bayer	

[CMJE](#) Data element required by the [International Committee of Medical Journal Editors](#) and the [World Health Organization ICTRP](#)

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