History of Changes for Study: NCT00936741

An Extension Study of CORLUX in the Treatment of Endogenous Cushing's Syndrome

Latest version (February 19, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's date link to see a rendering of the study for that version.
- Edits or deletions will be displayed in ~~red~~.
- Additions will be displayed in *green*.
- The yellow choices in the table indicate the study versions currently compared below. A yellow row indicates the study version being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.

Study Record Versions

Version	A	B	Date	Changes
1	◉	○	July 9, 2009	Nothing (earliest Version on record)
2	○	○	September 23, 2009	Study Status and Contacts/Locations
3	○	○	November 3, 2009	Study Status and Contacts/Locations
4	○	○	March 19, 2010	Study Status and Contacts/Locations
5	○	○	May 25, 2010	Study Status, Outcome Measures, Contacts/Locations and Study Description
6	○	○	July 7, 2010	Study Status and Contacts/Locations

Version	A	B	Date	Changes
7	○	○	July 16, 2010	Contacts/Locations and Study Status
8	○	○	June 22, 2011	Study Status
9	○	○	August 10, 2012	Recruitment Status, Sponsor/Collaborators and Study Status
10	○	◉	February 19, 2014	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Design, Study Description, Results, Eligibility and Conditions

Compare Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00936741
on Date: July 9, 2009 (v1)

Study Identification

Unique Protocol ID: C-1073-415

Brief Title: An Extension Study of CORLUX in the Treatment of Endogenous Cushing's Syndrome

Official Title: An Open Label Extension Study of the Efficacy and Safety of CORLUX® (Mifepristone) in the Treatment of the Signs and Symptoms of Endogenous Cushing's Syndrome

Secondary IDs:

Study Status

Record Verification: July 2009

Overall Status: Unknown status [Previously: Enrolling by invitation]

Study Start: July 2009

Primary Completion: August 2011 [Anticipated]

Study Completion: August 2011 [Anticipated]

First Submitted:	July 9, 2009
First Submitted that Met QC Criteria:	July 9, 2009
First Posted:	July 10, 2009 [Estimate]
Last Update Submitted that Met QC Criteria:	July 9, 2009
Last Update Posted:	July 10, 2009 [Estimate]

Sponsor/Collaborators

Sponsor:	Corcept Therapeutics
Responsible Party:	
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary:	Participants in study C-1073-400 (SEISMIC) will be invited to participate in this extension study to examine the long term safety of mifepristone in the treatment of the signs and symptoms of endogenous Cushing's syndrome. Total treatment duration may be up to 12 months.
Detailed Description:	Up to 50 subjects will receive mifepristone daily. Subjects completing 24 weeks of mifepristone treatment under Corcept protocol C1073-400 will be eligible to continue treatment for an additional 1 year. Assessments of safety, as evaluated by physical examinations, vital signs, laboratory tests and adverse events, will be made. Persistence of improvement in response to mifepristone treatment will also be evaluated during this extension study by assessing the continued or sustained improvement in the signs and symptoms of Cushing's syndrome.

Conditions

Conditions:	Cushing's Syndrome

Keywords:	Cushing's Disease Cushing's Syndrome Cushings Pituitary ACTH Adrenocorticotropic hormone Ectopic Adrenal adenoma Adrenal carcinoma Adrenal autonomy Cortisol Hypercortisolemia Cushinoid Moon facies Dorsalcervical fat Plethora Hirsutism Violaceous striae Hormone Contraceptive Endocrine Cushing Syndrome Ectopic ACTH Secretion

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Interventional Study Model:	Single Group Assignment
Number of Arms:	1
Masking:	None (Open Label)
Allocation:	N/A
Enrollment:	50 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Open-label mifepristone	Drug: mifepristone

Arms	Assigned Interventions
	mifepristone at doses from 300 mg/day up to 1200 mg/day daily Other Names: • CORLUX

Outcome Measures

Primary Outcome Measures:

1. Long term safety of mifepristone treatment
   12 months

Secondary Outcome Measures:

2. Persistence of therapeutic benefit due to continued mifepristone treatment
   12 months

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Have completed the Week 24 visit and the 6-Week Follow-up visit of Corcept Study C-1073-400.
- In the opinion of the Investigator, are expected to maintain clinical benefit from mifepristone.
- Women of childbearing potential have a negative serum pregnancy test at Entry.
- Women of childbearing potential must be willing to use non-hormonal, medically acceptable methods of contraception during the study.
- Are able to provide written informed consent
- Are able to return to the investigative site to complete the study evaluations outlined in the protocol.

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