Concerta (Methylphenidate) - To-Generic Switch Study

This study is ongoing, but not recruiting participants.

Sponsor:
Janssen Research & Development, LLC

Information provided by (Responsible Party):
Janssen Research & Development, LLC

ClinicalTrials.gov Identifier:
NCT02730572

First received: April 1, 2016
Last updated: NA
Last verified: April 2016
History: No changes posted

Purpose

The primary purpose of this study is to identify whether, after adjustment for confounders via stratification on a propensity score and adjustment for calendar year, the combined endpoint consisting of #1 to #4 (1. switching back to Concerta, 2. changing the use of immediate release [IR] methylphenidate, 3. beginning a new attention deficit hyperactivity disorder [ADHD] medication, or 4. stopping both Concerta and the long acting [LA] methylphenidate {authorized generic [AG] methylphenidate or equivalent generic [EG] methylphenidate} that was begun on the index date), differs between participants who switch from branded Concerta to the EG formulations versus participants who switch from branded Concerta to the AG formulation.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attention Deficit Disorder With Hyperactivity</td>
<td>Drug: Concerta</td>
</tr>
<tr>
<td></td>
<td>Drug: Concerta AG formulation</td>
</tr>
<tr>
<td></td>
<td>Drug: Concerta EG formulation</td>
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</tbody>
</table>

Study Type: Observational

Study Design: Observational Model: Cohort
            Time Perspective: Retrospective

Official Title: Concerta-to-Generic Switch Study

Resource links provided by NLM:

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder
Drug Information available for: Methylphenidate Methylphenidate hydrochloride

U.S. FDA Resources

Further study details as provided by Janssen Research & Development, LLC:

Primary Outcome Measures:

- Number of Participants Switching Back to Concerta [ Time Frame: 60 Days after index date (the date when participant switches from Concerta to an AG or EG) ] [ Designated as safety issue: No ]
- Number of Participants Changing the use of Immediate Release (IR) Methylphenidate [ Time Frame: 60 Days after index date (the date when participant switches from Concerta to an AG or EG) ] [ Designated as safety issue: No ]
- Number of Participants Starting a new Different Attention Deficit Hyperactivity Disorder (ADHD) Medication [ Time Frame: 60 Days before index date (the date when participant switches from Concerta to an AG or EG) ] [ Designated as safety issue: No ]
- Number of Participants Discontinuing the use of Both Concerta and the Study Drug to Which the Participant is Switched [ Time Frame: 60 Days after index date (the date when participant switches from Concerta to an AG or EG) ] [ Designated as safety issue: No ]

Secondary Outcome Measures:

- Number of Participants Changing the use of Immediate Release (IR) Methylphenidate [ Time Frame: 60 Days before and after index (the date when participant switches from Concerta to an AG or EG) ] [ Designated as safety issue: No ]
- Number of Participants Starting a new Different Attention Deficit Hyperactivity Disorder (ADHD) Medication [ Time Frame: 60 Days after index date (the date when participant switches from Concerta to an AG or EG) ] [ Designated as safety issue: No ]
- Number of Participants Changing an Established Methylphenidate [ Time Frame: 60 Days after index date (the date when participant switches from Concerta to an AG or EG) ] [ Designated as safety issue: No ]
- Number of Participants Having Outpatient Visits for ADHD [ Time Frame: 60 days after the index date (the date when participant switches from Concerta to an AG or EG) ] [ Designated as safety issue: No ]

Estimated Enrollment: 1000

Study Start Date: September 2015

Estimated Study Completion Date: December 2016

Estimated Primary Completion Date: December 2016 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Groups/Cohorts</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concerta to authorized generic (AG) formulation</td>
<td>Drug: Concerta</td>
</tr>
<tr>
<td>Participants in the Truven Commercial Claims and Encounters (CCAE) database</td>
<td>This is an observational study.</td>
</tr>
<tr>
<td>who enroll in the study will have a confirmed diagnosis of ADHD and</td>
<td>Participants who have been on Concerta for at least 60 days</td>
</tr>
<tr>
<td>continuously using Concerta for at least 60 days will be observed.</td>
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</tbody>
</table>
days. Participants who will switch from Concerta to AG formulation will be observed.

Other Name: Methylphenidate

Drug: Concerta AG formulation

This is an observational study.

Participants who have been on Concerta for at least 60 days and switch to authorized generic will be observed.

Other Name: Methylphenidate

Concerta to equivalent generic (EG) formulation

Participants in the Truven Commercial Claims and Encounters (CCAE) database who enroll in the study will have a confirmed diagnosis of ADHD and continuously using Concerta for at least 60 days. Participants who will switch from Concerta to EG formulation will be observed.

Other Name: Methylphenidate

Drug: Concerta

This is an observational study.

Participants who have been on Concerta for at least 60 days will be observed.

Other Name: Methylphenidate

Drug: Concerta EG formulation

This is an observational study.

Participants who have been on Concerta for at least 60 days and switch to equivalent generic will be observed.

Other Name: Methylphenidate

Detailed Description:

This is a retrospective cohort study based on a health claims database, the Truven Commercial Claims and Encounters (CCAE) database. Participants will enter the cohort when, after using Concerta continuously for at least 60 days after October 3, 2012, they receive a dispensing of the AG or EG formulation within 15 days of the end of the days of Concerta supplied. The date of that dispensing of the AG or EG formulation is the participants index date. This study will track various events, example, back-switches, and methylphenidate dose changes over time (the 60 days before the switch from Concerta to an AG or EG generic compared to the 60 days after that switch).

Eligibility

Ages Eligible for Study: 6 Years to 65 Years

Genders Eligible for Study: Both

Accepts Healthy Volunteers: No

Sampling Method: Non-Probability Sample

Study Population

Participants in the Truven Commercial Claims and Encounters (CCAE) database who enroll in the study will have a confirmed diagnosis of ADHD and continuously used Concerta brand of methylphenidate for at least 60 days and receive a dispensing of the AG or EG formulation within 15 days of the end of the days of Concerta supplied.

Criteria

Inclusion Criteria:

- Male or female participants 6 to 65 years of age
- Have been in the database continuously for at least 183 days after June 1, 2012
- Have a diagnosis of attention deficit hyperactivity disorder (ADHD)
- Use Concerta (a brand of methylphenidate) for at least 60 days and receive a dispensing of the authorized generic (AG) or equivalent generic (EG) formulation within 15 days of the end of the days of Concerta supplied. The date of that dispensing of the EG or AG formulation is the participants index date
- Have an index date greater than or equal to (>=) Dec 1, 2012 and less than or equal to (<=) Dec 3, 2014, the former to reflect the fact that the EG preparation became available in December, 2012, and the latter to allow 60 days follow up <= Jan 31, 2015, which is the end date for the available data

Exclusion Criteria:

- Their age or sex is not specified in the database
- At any time after June 1, 2012 and before their index date they receive a diagnosis of Renal insufficiency or Hepatic insufficiency or Schizophrenia or Bipolar disorder or mania or Anxiety or Glaucoma or Tourettes’s syndrome or Nervous tension or Narrowing of esophagus, stomach or intestine
- At any time from 183 days before they join the cohort to 60 days after their index date, they a) are diagnosed as pregnant; b) are dispensed any prescription medication commonly used to treat seizures or migraines c) are dispensed any antidepressant or antipsychotic medication
- At any time from 60 days before their index date to 60 days after their index date they a) Receive a dispensing of methylphenidate in any form other than a non-chewable tablet, example, if they receive methylphenidate as a patch, suspension, syrup, or chewable tablet b) Receive a dispensing of long acting (LA) methylphenidate other than Concerta, the AG formulation or an EG formulation
- Concerta is dispensed to the participant <= 3 days after the index date

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02730572

Sponsors and Collaborators
Janssen Research & Development, LLC

Investigators

Study Director: Janssen Research & Development, LLC Clinical Trial

More Information

No publications provided

Responsible Party: Janssen Research & Development, LLC
ClinicalTrials.gov Identifier: NCT02730572 History of Changes
Other Study ID Numbers: CR107709 RRA 14797
Study First Received: April 1, 2016
Last Updated: April 1, 2016
Health Authority: United States: Food and Drug Administration

Keywords provided by Janssen Research & Development, LLC:
Attention Deficit Hyperactivity Disorder
Methylphenidate
Additional relevant MeSH terms:
Attention Deficit Disorder with Hyperactivity
Hyperkinesis
Attention Deficit and Disruptive Behavior Disorders
Dyskinesias
Mental Disorders
Mental Disorders Diagnosed in Childhood
Nervous System Diseases
Neurologic Manifestations
Signs and Symptoms
Methylphenidate

ClinicalTrials.gov processed this record on April 05, 2016