Betrixaban Approved for Extended Venous Thromboembolism (VTE) Prophylaxis in Acutely Ill Medical Patients

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January 23, 2018

In 2017, betrixaban, a factor Xa inhibitor, became the first drug to be approved by the U.S. Food and Drug Administration (FDA) for hospital and extended duration (35 to 42 days) VTE prophylaxis.

FDA approval of betrixaban came after the drug was permitted a Fast Track designation followed by a Priority Review due to the significant findings noted in the "*Acute Medically Ill VTE (Venous Thromboembolism) Prevention with Extended Duration Betrixaban*" (APEX) trial.

APEX, a randomized double-blind, placebo-controlled trial, compared extended-duration betrixaban (35 to 42 days) to short-duration enoxaparin (6 to 14 days) for VTE in 7,513 acutely medically ill/ hospitalized patients with VTE risk factors. The outcome measures of the study were occurrence of asymptomatic proximal DVT or symptomatic DVT, non-fatal PE or VTE-related death.

The study revealed that although extended-duration Betrixaban showed no benefit over short-duration enoxaparin, (among a smaller cohort of acutely ill medical patients with an elevated D-dimer level), betrixaban reduced the incidence of DVT and PE for two larger cohorts, (elevated D-dimer or age >75 years and the overall study cohort), compared to those taking enoxaparin plus placebo. Participants on extended-duration betrixaban showed no significant increase in major bleeding compared to participants on short-duration enoxaparin.

Betrixaban is initiated with a single dose of 160 mg on day 1, followed by 80 mg once daily, taken with food, for 35 to 42 days at the same time each day.

Click on the links below for more information on betrixaban and the APEX trial:

http://www.nejm.org/doi/pdf/10.1056/NEJMoa1601747 [1]

https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm564422.htm [2]

http://www.ahjonline.com/article/S0002-8703(13)00786-2/pdf [3]

http://circ.ahajournals.org/content/early/2016/11/14/CIRCULATIONAHA.116.025427 [4]

Links
[1] http://www.nejm.org/doi/pdf/10.1056/NEJMoa1601747
[2] https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm564422.htm
[3] http://www.ahjonline.com/article/S0002-8703(13)00786-2/pdf
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