Risk of angioedema associated with levetiracetam compared with phenytoin
Overview of Research Question

Purpose:

To evaluate angioedema risk in seizure disorder patients exposed to levetiracetum compared with those exposed to phenytoin sodium. In late 2015, the Food and Drug Administration raised a potential link between levetiracetum and angioedema through their review of spontaneous reporting data.

Angioedema is a rare, rapid swelling of the face, mouth, tongue and throat and is potentially fatal.

Phenytoin is a common first-line anti-seizure treatment with no label warning for angioedema after 60 years on the market.

Primary hypothesis:

There is no difference in incidence risk of angioedema in new-user, seizure disorder patients of levetiracetum and phenytoin during drug exposure.
What is angioedema?
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Study Population / design

*Inclusion:*

Prior diagnosis of seizure disorder
First exposure to levetiracetum or phenytoin (index date)
No prior diagnosis angioedema
At least 183 days of observation time prior to the index date

*Risk model:*

Propensity-score (variable) matched
Cox proportional hazard models
Time-at-risk censored at end of initial drug exposure era or end of observation
100 negative controls to assess residual bias