National, centralised hospital datasets can inform clinical trial outcomes in prostate cancer: a pilot study in the STAMPEDE trial

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WIN conference 24/01/17
University of Warwick
Aim

• Develop a method to identify major clinical trial events in prostate cancer

• Testing if clustering of routinely collected NHS data correlates with these major clinical events
Research stage 1
Data sources

• Hospital clinical records
• NHS England Hospital Episode Statistics (HES)
• Clinical trial Case Report Forms (CRFs)
Patients

• STAMPEDE patients

• Queen Elizabeth Hospital Birmingham

• Patients stage 1 analysis: 5
Method

1. CLINICAL NOTES BASED ANALYSIS - 3 STAMPEDE patients

2. CLUSTERING

3. MODEL RULES

4. ROUTINE NHS DATA ANALYSIS

5. CLINICAL TRIAL CASE REPORT FORMS
Method cont.

6. ROUTINE DATA ANALYSIS – 2 STAMPEDE patients

7. MODEL VERIFICATION

8. MODEL REFINEMENT

9. CONFIRMED ROUTINE DATA ACCURACY
Results

A

Medical record review

Progressive Disease Events

Routine hospital statistic data

Trial Case Report Forms

B

Medical record review

Skeletal Related Events

Routine hospital statistic data

Trial Case Report Forms
Is HES data accurate enough to be used for trial purposes?
# Accuracy

Routine data was 75% accurate.

<table>
<thead>
<tr>
<th>Data</th>
<th>Number events</th>
<th>% accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total confirmed events</td>
<td>199</td>
<td>REFERENCE</td>
</tr>
<tr>
<td>Routine hospital statistics</td>
<td>149</td>
<td>75</td>
</tr>
<tr>
<td>Medical record review</td>
<td>191</td>
<td>96</td>
</tr>
</tbody>
</table>
Overall results cont.

Events coincided with routine data clustering

Routine hospital statistics data found:

• 71% of progressive events (10/14)
• 4 extra events that trial data missed
• missed 4 events (but further model refinement using SRE coding identified 2 of these)
• 4 SREs not found in trial data
Research stage 2
Stage 2 (in progress)

1) Algorithm creation
2) Algorithm validation: 50 STAMPEDE patients
3) Analysis: Compare events from routine data output to trial data

Stage 3: Further validation on >150 patients

Stage 4: Validation: all England patients
Summary

Algorithmic analysis of routine data:

• identified more events than traditional trial data
• identified the majority of events compared to note review
• aided the collection of Skeletal Related Event data

With suitable testing HES can be used for primary clinical trial data
References


