Development of an international observational study programme to describe the management and outcomes of mild stroke and transient ischaemic attack in routine clinical practice

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Introduction

• Patients with mild stroke/transient ischaemic attack (TIA) are at high risk of recurrent events.
• The Assessment of Real-world Evidence in Stroke/TIA (ARES) programme aims to characterize the management and outcomes of patients with mild stroke/TIA in real-world clinical practice in multiple countries around the world.
• Development of the ARES programme requires identification of suitable data sources that can provide consistent and/or complementary information in different countries and settings.

Objective

• To identify suitable data sources for the ARES programme.

Methods

• Applying a validated Systematic Understanding of Real-world Evidence (SURE) methodology,1,2 suitable data sources (cohorts, registries and databases) were identified and characterized by systematic literature and web searches, supplemented with e-mail and telephone contact (Figure 1).
• Data sources were recommended if they:
  – were active, representative and accessible
  – recorded National Institutes of Health Stroke Scale (NIHSS) scores or age, blood pressure, clinical features of TIA, duration of TIA and diabetes (ABCD2) scores
  – reported health resource utilization, ischaemic events and death during follow-up of at least 90 days (either direct or via linkage).
• The programme of included studies was finalized with input from principal investigators.

Results

• More than 2900 publications and 300 websites were screened, and 16 registries, 17 cohort studies and 43 databases were evaluated (Figure 2).
• Nine data sources from seven countries were recommended, with seven complementary sources from six countries being included (Table 1).
• Based on a globally agreed study design concept, study protocols for each data source were developed locally and are currently being implemented.
• The ARES programme target population will be patients with mild ischaemic stroke (NIHSS score ≤5) or high-risk TIA (ABCD2 score ≥4).

Figure 2. Data source selection process.

Data source characteristics were catalogued (extracted) and evaluated for quality, suitability and accessibility. For databases, data owners were contacted (queried) directly by e-mail and telephone, multiple times if necessary.

Conclusions

• Seven complementary data sources, from six countries, were identified for the ARES programme using the SURE methodology with input from principal investigators.
• The ARES programme will provide observational data from contemporary populations with mild stroke/TIA in real-world clinical practice.
• Studies will be reported individually owing to differences in the nature of the data sources.

Table 1. Data sources included in the ARES programme.

<table>
<thead>
<tr>
<th>Country</th>
<th>Data source</th>
<th>Population</th>
<th>Follow-up</th>
<th>Number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>Get With The Guidelines® – Stroke and AVAIL</td>
<td>In-hospital clinical registry covering 1600 hospitals</td>
<td>≥3 months, ≤10 years</td>
<td>≥800</td>
</tr>
<tr>
<td>China</td>
<td>National Stroke Registry</td>
<td>132 hospitals in 27 provinces</td>
<td>Inpatient, can be linked to Medicare</td>
<td>&gt;800</td>
</tr>
<tr>
<td>Japan</td>
<td>Fukuoka Stroke Registry</td>
<td>7 stroke centres in the Fukuoka region</td>
<td>Long term</td>
<td>&gt;500</td>
</tr>
<tr>
<td>South Korea</td>
<td>Clinical Research Center for Stroke – 5th Division Registry</td>
<td>12 academic and regional stroke centres</td>
<td>≤3 months</td>
<td>&gt;15 000</td>
</tr>
<tr>
<td>Sweden</td>
<td>Rikstoke</td>
<td>All Swedish hospitals admitting patients with acute stroke</td>
<td>Long term, can be linked to other Swedish registries</td>
<td>&gt;150 000</td>
</tr>
<tr>
<td>Germany</td>
<td>Erlangen Community Stroke Registry</td>
<td>Erlangen community</td>
<td>≥3 months, ≤10 years</td>
<td>&gt;800</td>
</tr>
</tbody>
</table>

ARES, Assessment of Real-world Evidence in Stroke/TIA; AVAIL, Adherence eValuation After Ischaemic stroke Longitudinal study.

References


Acknowledgements

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Disclosures

Saga Johansson, Mogens Westergaard and Em Jennings are employees of AstraZeneca. Chris C Winchester is an employee of Oxford PharmaGenesis, which provides data source assessment services and has received funding from AstraZeneca. Anja Becher is a contracted employee of Oxford PharmaGenesis and Kate Young was an employee of Oxford PharmaGenesis at the time the research was conducted.