Feasibility of Recruiting Subjects for Acute Spinal Cord Injury Clinical Trials in Canada

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Conflict of Interest Disclosures

• Local lead for RHSCIR (Halifax, Nova Scotia)
  • Funding from RHI

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Challenges of SCI Trials

• Many neuroprotective agents must be administered within 12 hours or less from time of injury
• Patients may be excluded 2° to concomitant injuries such as TBI or polytrauma which preclude assessment
• Many patients have some improvement – challenge of determining treatment efficacy vs. spontaneous recovery
• Requires large enrollment numbers to overcome
Using a Prospective Registry to Determine SCI Trial Feasibility

- Rick Hansen Spinal Cord Injury Registry (RHSCIR) – prospective SCI registry
- Lee et al (2012) – used VGH local data to examine SCI trial feasibility at their centre
- First to define proportion of cases eligible for SCI trials - may differ at other centres due to geographic and population differences

Methods

Used national RHSCIR to project enrollment potential for SCI trials within Canada

- 2008-2013
- 18 acute centres across Canada
- Excluded those with characteristics that typically preclude trial participation
  - age <18 or >75 years
  - penetrating injuries
Methods

Applied trial inclusion/exclusion criteria to RHSCIR participants:

- STASCIS
- Riluzole
- Sygen
- Cethrin
- NOGO
- Minocycline
Exclusion Based on Comorbidities

- RHSCIR collects data based on Charlson Comorbidity Index
  - Reviewed to determine whether serious enough to potentially exclude from trial participation
Comorbidities - Serious

- Myocardial infarction
- Congestive heart failure
- Peripheral vascular disease
- Cerebrovascular disease
- Dementia
- Chronic pulmonary disease
- Liver disease mild
- Diabetes
- Hemiplegia
- Renal disease moderate or severe
- Diabetes with end organ damage
- Any malignancy

- Leukemia
- Malignant lymphoma
- Liver disease moderate or severe
- Metastatic solid malignancy
- AIDS
- Poliomyelitis
- Achondroplasia
- Mental retardation
- Major psychiatric conditions
- Cerebral palsy
- Muscular dystrophy
- Pre-existing SCI
Comorbidities - Non-Serious

- Ulcer disease
- Osteoarthritis/degenerative arthritis
- Osteoporosis
Key Eligibility Criteria

Results
Enrolled Pts with Admission Data

2751

< 18 or > 75 y.o.

2449

301

Missing - 1

Did not receive acute care at RHSCIR site

2311

138

Missing - 0

Penetrating Injury

2176

60

Missing - 75
Study-Specific Criteria

Results
STASCIS (9 years, 313 patients)

- C2-T1: 1106
- Injury to RHSCIR acute < 24 h: 828
- Surgery (Y): 411
- Surgery within 7 days: 387
- Total: 2176
- 1070
- 278
- 417
- 24

17.78%
Riluzole (enrolling since 2012)

- **Time of injury to 1st acute RHSCIR < 12 h**
  - **C4-C8**: 312
  - **AIS A, B or C**: 549
  - **14.34%**
Sygen (5 years, 797 patients)

- Total: 2176
- C1-T9: 1352
- LEMS ≤ 15/25: 838
- One/both LEMS ≤ 15/25: 514
- 38.51%
Cethrin (2.5 years, 48 patients)

- 2176
- C4-T12: 1354, 822
- AIS A: 543, 811
- Surgery (Y): 344, 199
- Surgery within 7 days: 306, 38

14.06%
Nogo

2176

C5-T11

920
1256

AIS A

418
502

19.21%
### Potential Cases from RHSCIR Sites by Year

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Exclusion Based on Comorbidities

Results
Comorbidities

- No Comorbidity: 72%
- At Least One Serious: 24%
- Non-Serious: 4%

- One: 74%
- Two: 19%
- Three or more: 7%
Comorbidities - GCS

- GCS 13-15: 92%
- GCS 12 or less: 8%
Limitations

• Real-life factors which may affect recruitment in practice:
  • Alcohol or drug use
  • Patient willingness to participate
  • Likelihood for follow-up
Conclusions

• SCI trials are feasible in Canada using multi-centre collaboration
• RHSCIR data may be helpful in planning clinical trials
  • How many sites
  • Location of sites
  • Duration of study
Questions?