2015 AAIC WW-ADNI Meeting, Washington DC

K-ADNI Update

July 17th, 2015

Seong Yoon Kim, Seol Hee Han, Duk L. Na
Updates from K-ADNI

- Homepage and eCRF site
  - www.k-adni.org for information portal for general population
  - http://kadni.e-trial.co.kr/
### Target Subjects

<table>
<thead>
<tr>
<th>Cognition</th>
<th>WMH on MRI</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>HC, aMCI, vMCI, AD, SIVD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No cognitive impairment</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>Mild cognitive impairment</td>
<td>200</td>
<td>300</td>
</tr>
<tr>
<td>Mild dementia</td>
<td>50</td>
<td>150</td>
</tr>
<tr>
<td>Major Type</td>
<td>AD</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mixed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>SIVD</td>
<td></td>
</tr>
</tbody>
</table>
## Inclusion / Exclusion criteria

<table>
<thead>
<tr>
<th>Category</th>
<th>Evaluation Applied</th>
<th>Healthy Control (HC)</th>
<th>Mild Cognitive Impairment (MCI)</th>
<th>Dementias</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>$\geq -1.5 \text{ SD in Age, Gender, Edu norm}$</td>
<td>$\geq 24$</td>
<td>$18 \leq$ and $&lt; 26$</td>
</tr>
<tr>
<td>Screening Test</td>
<td>K-MMSE</td>
<td>$\geq 24$</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cognitive Test</td>
<td>SVLT-E</td>
<td>$-1.5 \leq$ and $&lt; -1.0$ SD</td>
<td>$&lt; -1.5 \text{ SD}$</td>
<td></td>
</tr>
<tr>
<td>ADL Impairment</td>
<td>Clinician’s Evaluation</td>
<td>$0$</td>
<td>$0.5$</td>
<td>ADL Impaired</td>
</tr>
<tr>
<td>Severity</td>
<td>CDR Rating</td>
<td>$-0$</td>
<td>$-0$</td>
<td>0.5 or 1.0</td>
</tr>
<tr>
<td>Diagnostic Criteria</td>
<td>Probable AD by NINCDS-ADRDA</td>
<td>$-0$</td>
<td>$-0$</td>
<td>Applied</td>
</tr>
<tr>
<td>Vascularity</td>
<td>Vasc. Risk Factors: more than 2 out of 5 (regardless of control): HTN / DM / Dyslipid / Obesity (BMI &gt; 25) / Smoking AND WMH Moderate or higher on MRI AND Clinical judgment: Time correlation and Causality</td>
<td>$-0$</td>
<td>$-0$</td>
<td>Yes</td>
</tr>
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<td></td>
<td></td>
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<td>≥ -1.5 SD in Age,</td>
<td>E-MCI V-E-MCI L-MCI V-L-MCI</td>
<td>AD</td>
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<td></td>
<td></td>
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**Note:**
- **AD:** Alzheimer’s Disease
- **SIVD:** Subcortical Vascular Impairment
Timeline of K-ADNI

- Year 3 (Nov. 2014 ~ Oct. 2015) of 6 year project
  - Original time line

<table>
<thead>
<tr>
<th>Year 2013</th>
<th>Year 2014</th>
<th>Year 2015</th>
<th>Year 2016</th>
<th>Year 2017</th>
<th>Year 2018</th>
</tr>
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<td>Infra-structure Setup</td>
<td>Subject Recruit</td>
<td>Follow Up for 36 months</td>
<td></td>
<td></td>
<td></td>
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Timeline of K-ADNI

- Year 3 (Nov. 2014 ~ Oct. 2015) of 6 year project
  - Original time line
    - 2013
    - 2014
    - 2015
    - 2016
    - 2017
    - 2018

- It turned out to be...
  - 2013
  - 2014
  - 2015
  - 2016
  - 2017
  - 2018
  - 2019

- Infra-structure Setup
- Subject Recruit
- Follow Up for 36 months
Updates from K-ADNI

- Subject recruitment still pending
  - Clinical sites ready for their first subjects.
  - MERS swept over Korean major hospitals for the last 2 months.
Updates from K-ADNI

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Updates from K-ADNI

- Major difficulties in K-ADNI clinical sites are:
  - Slow accustomization to ADNI protocol
    - Not very familiar to participating site staffs
## Clinical Evaluation

### US-ADNI
- Clinical Dementia Rating
- Everyday Cognition (eCOG)
- Geriatric Depression Scale
- Modified Hachinski
- Functional Assessment Questionnaire (FAQ)
- Neuropsychiatric Inventory Questionnaire (NPI)

### K-ADNI
- Clinical Dementia Rating
- K-eCOG
- Geriatric Depression Scale
- Modified Hachinski
- Functional Assessment Questionnaire (FAQ)
- Other functional
  - DAD, IQCODE
- Neuropsychiatric Inventory Questionnaire (NPI)
NP Tests

US-ADNI

- Alzheimer's Disease Assessment Scale: ADAS
- American NART
- Boston Naming Test: BNT
- Category fluency: Animal
- Clock DT
- Logical memory: Immediate + delayed recall
- MMSE, MoCA
- Rey AVLT
- TMT

K-ADNI

- Alzheimer's Disease Assessment Scale: ADAS
- -
- K-BNT
- Category fluency: Animal
- Clock DT
- Logical memory: subtituted for VLT-E
- MMSE, MoCA-K
- AVLT
- TMT
Updates from K-ADNI

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Updates from K-ADNI

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  ○ Slow accustomization to ADNI protocol
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  ○ eCRF system
    ■ Slow stabilization thru trial-and-error
Updates from K-ADNI

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  - Slow accustomization to ADNI protocol
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  - eCRF system
    - Slow stabilization thru trial-and-error
    - Collaboration between clinical, scientific, administrative, regulatory and IT staff essential
Updates from K-ADNI

● Major difficulties in K-ADNI clinical sites are:
  ○ Slow accustomization to ADNI protocol
    ■ Not very familiar to participating site staffs
  ○ eCRF system
    ■ Slow stabilization thru trial-and-error
    ■ Collaboration between clinical, scientific, administrative, regulatory and IT staff essential
    ■ Different design, implementation, data QA from previous drug trials, or cross-sectional registries.