DESIGNING & COMPLETING EFFICIENT RANDOMIZED CONTROLLED TRIALS

PRAPA KANAGARATNAM

TUES 9TH OCT HALL 6B
A novel approach to mapping the atrial ganglionated plexus network by generating a distribution probability atlas

Min-Young Kim MRCP1,2,3 | Markus B. Sikkel PhD1,2,3 | Ross J. Hunter PhD4 | Guy A. Haywood MD5 | David R. Tomlinson MD5 | Muzahir H. Tayebjee MD6 | Rheeda L. Ali PhD1,2 | Chris D. Cantwell PhD1,2 | Hanney Gonna MRCP1,2 | Belinda C. Sandler BSc, MRCP1,2 | Elaine Lim BSc2,3 | Guy Furniss MRCP5 | Dimitrios Panagopoulos MRCP5 | Gordon Begg MRCP5 | Gurpreet Dhillon MRCP5 | Nicola J. Hill6 | James O’Neill MRCP6 | Darrel P. Francis MD1,2,3 | Phang Boon Lim PhD1,2,3 | Nicholas S. Peters MD1,2,3 | Nick W. F. Linton PhD1,2,3 | Prapa Kanagaratnam PhD1,2,3
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### PROSPECTIVE MULTI-CENTRE TRIAL EXPERIENCE

<table>
<thead>
<tr>
<th>AVATAR-AF</th>
<th>RIPPLE-AT</th>
<th>ERASE-VT</th>
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<td><strong>Cryo-PVI without mapping vs standard cryo vs medical therapy</strong>&lt;br&gt;Target 321 pts recruited, FU complete&lt;br&gt;13 centres, UK&lt;br&gt;Results will be published 2019&lt;br&gt;Imperial College Trial Unit&lt;br&gt;BHF+Medtronic - £650K</td>
<td><strong>Ripple vs LAT mapping for AT ablation</strong>&lt;br&gt;Target 110pts recruited, acute study only&lt;br&gt;5UK + Lisbon&lt;br&gt;Results will be published APHRS next week&lt;br&gt;No Trials unit&lt;br&gt;Biosense -£80K</td>
<td><strong>Robotic VT substrate ablation vs medical therapy</strong>&lt;br&gt;Target 10 European centres ---&gt; 3 centres&lt;br&gt;Target 200pts -&gt;50pts&lt;br&gt;Terminated due to Hansen Medical administration&lt;br&gt;Imperial College Trial Unit withdrew due to slow recruitment&lt;br&gt;Struggling to publish due to perceived underpowering&lt;br&gt;Hansen Medical 300K -&gt;100K</td>
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PLANNING THE STUDY

HYPOTHESIS

NUMBER OF PATIENTS REQUIRED TO PRODUCE ADEQUATE EVENTS

HOW MANY CENTRES WOULD BE ABLE/PREPARED TO DO PROTOCOL

IS A TRIALS UNIT REQUIRED? BLINDING REQUIRED

FUNDING CHARITABLE BODIES VS INDUSTRY PORTFOLIO

IS IT FEASIBLE?

RECRUITMENT & FOLLOW UP TIMESCALE

COST

ARE YOU COMMITTED TO IT?
RECRUITMENT

• Do not underestimate how much motivational work is required

• Recruitment plan should be in place early

• Recruitment target chart
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