The Joint UK Societies Working Group on Renal Denervation.
Initial response to the Medtronic Symplicity HTN3 announcement.

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Symplicity HTN3 Trial of renal denervation in resistant hypertension.

- Medtronic announced on January 9th 2014 that a large randomised controlled trial of renal denervation in 530 people with resistant hypertension using the unipolar Symplicity Catheter has not met the primary endpoint for blood pressure reduction.
- The study met the safety endpoint and there is no evidence of harm at 6 months.
- Medtronic has suspended its own regulatory trials in resistant hypertension worldwide while it assesses the results of Symplicity HTN3 and consults with international experts. This is a sensible approach as they have very similar designs. Trials in other conditions such as heart failure are continuing.
- The response of the other renal denervation device manufacturers is unclear at present but at least one (Covidien) has withdrawn its product from the market.
- There are no data available at this time other than information above.

The Joint UK Societies current perspective:

- Data from the trial will be reported at a forthcoming international meeting and in peer reviewed journals. To make a proper evaluation of the implications of this trial for renal denervation we need to thoroughly review the results of Symplicity HTN3 and not rush to hasty conclusions.
- While we await the data from Symplicity HTN3, we recommend a temporary moratorium on renal denervation procedures for all cases as part of routine care in the NHS and private practice in the UK.
- We will make a further statement when the data is released.
- Our proposed temporary moratorium should not apply to clinical trials as there are many other technologies that are in development for renal denervation (including by Medtronic). Some randomised controlled trials are starting or underway and the UK is committed to leading, supporting and participating in well-designed trials. It is now even more important than ever that properly controlled randomised controlled trials are undertaken to assess the future role of renal denervation in the treatment of resistant hypertension.