

## **Additional file 2.** Study organization

### Steering Committee

Hiroshi Ito (Chair), Kazufumi Nakamura, Toru Miyoshi, Kentaro Ejiri, Okayama University Graduate School of Medicine, Dentistry and Pharmaceutical Sciences, Okayama, Japan; Satoru Sakuragi, Iwakuni Clinical Center, Yamaguchi, Japan; Mitsuru Munemasa, Okayama Medical Center, Okayama, Japan; Seiji Nanba, Okayama Rosai Hospital, Okayama, Japan; Tomosato Suezawa, Takamatsu Red Cross Hospital, Kagawa, Japan; Atsushi Takaishi, Mitoyo General Hospital, Kagawa, Japan.

### Statistical consulting

Tetsutaro Hamano, P4 Statistics Co. Ltd., Tokyo, Japan.

### Clinical Event Committee

Masayuki Doi, Kagawa Prefectural Central Hospital, Kagawa, Japan; Takefumi Oka, Tsuyama Central Hospital, Okayama, Japan.

### Data Monitoring

Given that invasive intervention will not be performed in this study, data monitoring is not planned.