



## Clinical trial results:

**Randomized double-blind placebo-controlled trial on the efficiency of a single dose dexamethasone in reducing the postembolization syndrome in men undergoing prostatic artery embolization for benign prostatic hyperplasia**

### Summary

|                          |                  |
|--------------------------|------------------|
| EudraCT number           | 2020-000915-53   |
| Trial protocol           | DK               |
| Global end of trial date | 03 November 2022 |

### Results information

|                                |                 |
|--------------------------------|-----------------|
| Result version number          | v1 (current)    |
| This version publication date  | 25 October 2024 |
| First version publication date | 25 October 2024 |

### Trial information

#### Trial identification

|                       |         |
|-----------------------|---------|
| Sponsor protocol code | DEXAPAE |
|-----------------------|---------|

#### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT04588857 |
| WHO universal trial number (UTN)   | -           |

Notes:

### Sponsors

|                              |  |
|------------------------------|--|
| Sponsor organisation name    | Rigshospitalet   |
| Sponsor organisation address | Blegdamsvej 9, Copenhagen, Denmark, 2100   |
| Public contact               | The Department of Radiology and The Department of Urology, Rigshospitalet, +45 35458789, andreas.roeder@regionh.dk |
| Scientific contact           | The Department of Radiology and The Department of Urology, Rigshospitalet, +45 35458789, andreas.roeder@regionh.dk |

Notes:

### Paediatric regulatory details

|  |    |
|--|----|
| Is trial part of an agreed paediatric investigation plan (PIP)       | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

## Results analysis stage

|  |                  |
|--|------------------|
| Analysis stage                                       | Final            |
| Date of interim/final analysis                       | 03 November 2022 |
| Is this the analysis of the primary completion data? | Yes              |
| Primary completion date                              | 03 May 2022      |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 03 November 2022 |
| Was the trial ended prematurely?                     | Yes              |

Notes:

## General information about the trial

Main objective of the trial:

Reduction in post-procedural fever and pain with dexamethasone in patients undergoing prostatic artery embolization (PAE) for benign prostatic hyperplasia (BPH)

Protection of trial subjects:

Participation in the trial was voluntary and did not affect the individual's assessment and treatment process. The participants were informed, both orally and in writing, of the study's purpose and implications. Prior to participation, the trial participants signed a consent form. Participants could withdraw their consent at any time without explanation. The standard clinical procedure was the same for trial participants.

Background therapy: -

Evidence for comparator: -

|   |               |
|---|---------------|
| Actual start date of recruitment                          | 11 March 2021 |
| Long term follow-up planned                               | No            |
| Independent data monitoring committee (IDMC) involvement? | Yes           |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |             |
|--------------------------------------|-------------|
| Country: Number of subjects enrolled | Denmark: 31 |
| Worldwide total number of subjects   | 31          |
| EEA total number of subjects         | 31          |

Notes:

### Subjects enrolled per age group

|   |    |
|---|----|
| In utero                                  | 0  |
| Preterm newborn - gestational age < 37 wk | 0  |
| Newborns (0-27 days)                      | 0  |
| Infants and toddlers (28 days-23 months)  | 0  |
| Children (2-11 years)                     | 0  |
| Adolescents (12-17 years)                 | 0  |
| Adults (18-64 years)                      | 5  |
| From 65 to 84 years                       | 26 |

|                   |   |
|-------------------|---|
| 85 years and over | 0 |
|-------------------|---|

## Subject disposition

### Recruitment

Recruitment details:

All patients referred to the Department of Urology, Rigshospitalet with lower urinary tract symptoms, and who were candidates for prostatic artery embolisation were considered for trial recruitment.

### Pre-assignment

Screening details:

Inclusion criteria mimicked the standard PAE eligibility criteria at our institution. Exclusion criteria consisted of current urological contraindications to PAE, contraindications for catheter-based interventions and contraindications for high-dose steroid administration. Written informed consent was obtained from all participants prior to inclusion.

### Period 1

|                              |  |
|------------------------------|--|
| Period 1 title               | Intervention (Overall period) (overall period) |
| Is this the baseline period? | Yes  |
| Allocation method            | Randomised - controlled                        |
| Blinding used                | Double blind                                   |
| Roles blinded                | Subject, Investigator, Carer                   |

### Arms

|                              |            |
|------------------------------|------------|
| Are arms mutually exclusive? | Yes        |
| <b>Arm title</b>             | Active Arm |

Arm description:

Received trial medicine dexamethasone 24 mg as a single intravenous bolus dose

|  |                                 |
|--|---------------------------------|
| Arm type                               | Active comparator               |
| Investigational medicinal product name | Dexavit 4mg/ml                  |
| Investigational medicinal product code |                                 |
| Other name                             |                                 |
| Pharmaceutical forms                   | Solution for injection/infusion |
| Routes of administration               | Intravenous use                 |

Dosage and administration details:

24 mg, single dose

|                  |             |
|------------------|-------------|
| <b>Arm title</b> | Placebo arm |
|------------------|-------------|

Arm description:

Received intravenous saline

|  |                                 |
|--|---------------------------------|
| Arm type                               | Placebo                         |
| Investigational medicinal product name | Sodium Chloride 0.9%            |
| Investigational medicinal product code |                                 |
| Other name                             |                                 |
| Pharmaceutical forms                   | Solution for injection/infusion |
| Routes of administration               | Intravenous use                 |

Dosage and administration details:

6 ml, single dose

| <b>Number of subjects in period 1</b> | Active Arm | Placebo arm |
|---------------------------------------|------------|-------------|
| Started                               | 16         | 15          |
| Completed                             | 16         | 15          |

## Baseline characteristics

### Reporting groups

|                       |                               |
|-----------------------|-------------------------------|
| Reporting group title | Intervention (Overall period) |
|-----------------------|-------------------------------|

Reporting group description: -

| Reporting group values                             | Intervention (Overall period) | Total |  |
|--|-------------------------------|-------|--|
| Number of subjects                                 | 31                            | 31    |  |
| Age categorical                                    |                               |       |  |
| Units: Subjects                                    |                               |       |  |
| In utero   |                               | 0     |  |
| Preterm newborn infants (gestational age < 37 wks) |                               | 0     |  |
| Newborns (0-27 days)                               |                               | 0     |  |
| Infants and toddlers (28 days-23 months)           |                               | 0     |  |
| Children (2-11 years)                              |                               | 0     |  |
| Adolescents (12-17 years)                          |                               | 0     |  |
| Adults (18-64 years)                               |                               | 0     |  |
| From 65-84 years                                   |                               | 0     |  |
| 85 years and over                                  |                               | 0     |  |
| Age continuous                                     |                               |       |  |
| Units: years                                       |                               |       |  |
| median   | 70                            |       |  |
| inter-quartile range (Q1-Q3)                       | 66 to 75                      | -     |  |
| Gender categorical                                 |                               |       |  |
| Units: Subjects                                    |                               |       |  |
| Female   | 0                             | 0     |  |
| Male   | 31                            | 31    |  |

## End points

### End points reporting groups

|  |             |
|--|-------------|
| Reporting group title  | Active Arm  |
| Reporting group description:   |             |
| Received trial medicine dexamethasone 24 mg as a single intravenous bolus dose |             |
| Reporting group title  | Placebo arm |
| Reporting group description:   |             |
| Received intravenous saline  |             |

### Primary: Rectal temperature (in degrees Celsius) at 2 days following intervention

|                               |  |
|-------------------------------|--|
| End point title               | Rectal temperature (in degrees Celsius) at 2 days following intervention |
| End point description:        |  |
| End point type                | Primary  |
| End point timeframe:          |  |
| 2 days following intervention |  |

| End point values                     | Active Arm      | Placebo arm     |  |  |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type                   | Reporting group | Reporting group |  |  |
| Number of subjects analysed          | 16              | 15              |  |  |
| Units: Degree Celsius                |                 |                 |  |  |
| arithmetic mean (standard deviation) | 37.19 (± 0.59)  | 37.54 (± 0.7)   |  |  |

### Statistical analyses

|   |                          |
|---|--------------------------|
| Statistical analysis title              | Independent t-test       |
| Comparison groups                       | Active Arm v Placebo arm |
| Number of subjects included in analysis | 31                       |
| Analysis specification                  | Pre-specified            |
| Analysis type                           | superiority              |
| P-value                                 | < 0.05                   |
| Method                                  | t-test, 2-sided          |
| Confidence interval                     |                          |

### Primary: Pain Severity score on Brief Pain Inventory—Short Form (BPI-SF) in first 5 days following the procedure

|                 |   |
|-----------------|---|
| End point title | Pain Severity score on Brief Pain Inventory—Short Form (BPI-SF) in first 5 days following the procedure |
|-----------------|---|

End point description:

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

First 5 days following intervention

| End point values                     | Active Arm      | Placebo arm     |  |  |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type                   | Reporting group | Reporting group |  |  |
| Number of subjects analysed          | 16              | 15              |  |  |
| Units: Points                        |                 |                 |  |  |
| arithmetic mean (standard deviation) | 2.94 (± 2.1)    | 1.88 (± 1.36)   |  |  |

### Statistical analyses

|   |                          |
|---|--------------------------|
| Statistical analysis title              | Independent t-test       |
| Comparison groups                       | Placebo arm v Active Arm |
| Number of subjects included in analysis | 31                       |
| Analysis specification                  | Pre-specified            |
| Analysis type                           | superiority              |
| P-value                                 | < 0.05                   |
| Method                                  | t-test, 2-sided          |
| Confidence interval                     |                          |

### Primary: Pain Interference score on Brief Pain Inventory—Short Form (BPI-SF) in first 5 days following the procedure

|                 |   |
|-----------------|---|
| End point title | Pain Interference score on Brief Pain Inventory—Short Form (BPI-SF) in first 5 days following the procedure |
|-----------------|---|

End point description:

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

First 5 days following intervention

| End point values                     | Active Arm      | Placebo arm     |  |  |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type                   | Reporting group | Reporting group |  |  |
| Number of subjects analysed          | 16              | 15              |  |  |
| Units: Points                        |                 |                 |  |  |
| arithmetic mean (standard deviation) | 2.97 (± 2.2)    | 2.04 (± 1.36)   |  |  |



### Statistical analyses

|   |                          |
|---|--------------------------|
| <b>Statistical analysis title</b>       | Independent t-test       |
| Comparison groups                       | Active Arm v Placebo arm |
| Number of subjects included in analysis | 31                       |
| Analysis specification                  | Pre-specified            |
| Analysis type                           | superiority              |
| P-value                                 | < 0.05                   |
| Method                                  | t-test, 2-sided          |
| Confidence interval                     |                          |

### Secondary: Paracetamol dose for the first 5 days

|                                     |                                       |
|-------------------------------------|---------------------------------------|
| End point title                     | Paracetamol dose for the first 5 days |
| End point description:              |                                       |
| End point type                      | Secondary                             |
| End point timeframe:                |                                       |
| First 5 days following intervention |                                       |

|                                       |                     |                     |  |  |
|---------------------------------------|---------------------|---------------------|--|--|
| <b>End point values</b>               | Active Arm          | Placebo arm         |  |  |
| Subject group type                    | Reporting group     | Reporting group     |  |  |
| Number of subjects analysed           | 16                  | 15                  |  |  |
| Units: Miligrams                      |                     |                     |  |  |
| median (inter-quartile range (Q1-Q3)) | 1750 (1175 to 2450) | 1600 (1000 to 2900) |  |  |

### Statistical analyses

|   |                          |
|---|--------------------------|
| <b>Statistical analysis title</b>       | Independent t-test       |
| Comparison groups                       | Active Arm v Placebo arm |
| Number of subjects included in analysis | 31                       |
| Analysis specification                  | Pre-specified            |
| Analysis type                           | superiority              |
| P-value                                 | < 0.05                   |
| Method                                  | t-test, 2-sided          |

**Secondary: Ibuprofen dose for the first 5 days**

|                 |                                     |
|-----------------|-------------------------------------|
| End point title | Ibuprofen dose for the first 5 days |
|-----------------|-------------------------------------|

|                        |  |
|------------------------|--|
| End point description: |  |
|------------------------|--|

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

|                      |  |
|----------------------|--|
| End point timeframe: |  |
|----------------------|--|

|                                     |  |
|-------------------------------------|--|
| First 5 days following intervention |  |
|-------------------------------------|--|

| End point values                      | Active Arm      | Placebo arm     |  |  |
|---------------------------------------|-----------------|-----------------|--|--|
| Subject group type                    | Reporting group | Reporting group |  |  |
| Number of subjects analysed           | 16              | 15              |  |  |
| Units: Miligrams                      |                 |                 |  |  |
| median (inter-quartile range (Q1-Q3)) | 80 (0 to 160)   | 0 (0 to 306)    |  |  |

**Statistical analyses**

|                            |                    |
|----------------------------|--------------------|
| Statistical analysis title | Independent t-test |
|----------------------------|--------------------|

|                   |                          |
|-------------------|--------------------------|
| Comparison groups | Active Arm v Placebo arm |
|-------------------|--------------------------|

|   |    |
|---|----|
| Number of subjects included in analysis | 31 |
|---|----|

|                        |               |
|------------------------|---------------|
| Analysis specification | Pre-specified |
|------------------------|---------------|

|               |             |
|---------------|-------------|
| Analysis type | superiority |
|---------------|-------------|

|         |        |
|---------|--------|
| P-value | < 0.05 |
|---------|--------|

|        |                 |
|--------|-----------------|
| Method | t-test, 2-sided |
|--------|-----------------|

|                     |  |
|---------------------|--|
| Confidence interval |  |
|---------------------|--|

**Secondary: C-reactive protein value at 2 days following the procedure**

|                 |  |
|-----------------|--|
| End point title | C-reactive protein value at 2 days following the procedure |
|-----------------|--|

|                        |  |
|------------------------|--|
| End point description: |  |
|------------------------|--|

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

|                      |  |
|----------------------|--|
| End point timeframe: |  |
|----------------------|--|

|                              |  |
|------------------------------|--|
| Day 2 following intervention |  |
|------------------------------|--|

| End point values                      | Active Arm      | Placebo arm     |  |  |
|---------------------------------------|-----------------|-----------------|--|--|
| Subject group type                    | Reporting group | Reporting group |  |  |
| Number of subjects analysed           | 16              | 15              |  |  |
| Units: Miligrams per liter            |                 |                 |  |  |
| median (inter-quartile range (Q1-Q3)) | 10 (5 to 33)    | 108 (54 to 161) |  |  |

### Statistical analyses

| Statistical analysis title              | Independent t-test       |
|---|--------------------------|
| Comparison groups                       | Active Arm v Placebo arm |
| Number of subjects included in analysis | 31                       |
| Analysis specification                  | Pre-specified            |
| Analysis type                           | superiority              |
| P-value                                 | < 0.05                   |
| Method                                  | t-test, 2-sided          |
| Confidence interval                     |                          |

### Secondary: IPSS at day 2 post procedure

|                        |                              |
|------------------------|------------------------------|
| End point title        | IPSS at day 2 post procedure |
| End point description: |                              |
| End point type         | Secondary                    |
| End point timeframe:   |                              |
| 2 days post procedure  |                              |

| End point values                     | Active Arm      | Placebo arm     |  |  |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type                   | Reporting group | Reporting group |  |  |
| Number of subjects analysed          | 16              | 15              |  |  |
| Units: Points                        |                 |                 |  |  |
| arithmetic mean (standard deviation) | 24.9 (± 6.9)    | 21.1 (± 6.8)    |  |  |

### Statistical analyses

| Statistical analysis title | Independent t-test       |
|----------------------------|--------------------------|
| Comparison groups          | Active Arm v Placebo arm |

|   |                 |
|---|-----------------|
| Number of subjects included in analysis | 31              |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority     |
| P-value                                 | < 0.05          |
| Method                                  | t-test, 2-sided |
| Confidence interval                     |                 |

### Secondary: IPSS at 5 days post procedure

|                        |                               |
|------------------------|-------------------------------|
| End point title        | IPSS at 5 days post procedure |
| End point description: |                               |
| End point type         | Secondary                     |
| End point timeframe:   |                               |
| Day 5 post procedure   |                               |

| End point values                     | Active Arm      | Placebo arm     |  |  |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type                   | Reporting group | Reporting group |  |  |
| Number of subjects analysed          | 16              | 15              |  |  |
| Units: Points                        |                 |                 |  |  |
| arithmetic mean (standard deviation) | 23.9 (± 8.5)    | 23.3 (± 7.2)    |  |  |

### Statistical analyses

|   |                          |
|---|--------------------------|
| <b>Statistical analysis title</b>       | Independent t-test       |
| Comparison groups                       | Active Arm v Placebo arm |
| Number of subjects included in analysis | 31                       |
| Analysis specification                  | Pre-specified            |
| Analysis type                           | superiority              |
| P-value                                 | < 0.05                   |
| Method                                  | t-test, 2-sided          |
| Confidence interval                     |                          |

### Secondary: Nausea in the first 5 days post procedure

|                                     |   |
|-------------------------------------|---|
| End point title                     | Nausea in the first 5 days post procedure |
| End point description:              |   |
| End point type                      | Secondary                                 |
| End point timeframe:                |   |
| First 5 days following intervention |   |

|                             |                 |                 |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| <b>End point values</b>     | Active Arm      | Placebo arm     |  |  |
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 16              | 15              |  |  |
| Units: Yes/no               | 9               | 11              |  |  |

### Statistical analyses

|   |                             |
|---|-----------------------------|
| <b>Statistical analysis title</b>       | Pearsons's Chi-squared test |
| Comparison groups                       | Active Arm v Placebo arm    |
| Number of subjects included in analysis | 31                          |
| Analysis specification                  | Pre-specified               |
| Analysis type                           | superiority                 |
| P-value                                 | < 0.05                      |
| Method                                  | t-test, 2-sided             |

### Secondary: Dysuria in the first 5 days post procedure

|                                     |  |
|-------------------------------------|--|
| End point title                     | Dysuria in the first 5 days post procedure |
| End point description:              |  |
| End point type                      | Secondary                                  |
| End point timeframe:                |  |
| First 5 days following intervention |  |

|                             |                 |                 |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| <b>End point values</b>     | Active Arm      | Placebo arm     |  |  |
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 16              | 15              |  |  |
| Units: Yes/no               | 14              | 13              |  |  |

### Statistical analyses

|                                   |                             |
|-----------------------------------|-----------------------------|
| <b>Statistical analysis title</b> | Pearsons's Chi-squared test |
| Comparison groups                 | Active Arm v Placebo arm    |

|   |                 |
|---|-----------------|
| Number of subjects included in analysis | 31              |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority     |
| P-value                                 | < 0.05          |
| Method                                  | t-test, 2-sided |

### Secondary: Urinary tract infection in the first 5 days post procedure

|                                     |  |
|-------------------------------------|--|
| End point title                     | Urinary tract infection in the first 5 days post procedure |
| End point description:              |  |
| End point type                      | Secondary  |
| End point timeframe:                |  |
| First 5 days following intervention |  |

| End point values            | Active Arm      | Placebo arm     |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 16              | 15              |  |  |
| Units: Yes/no               | 1               | 0               |  |  |

### Statistical analyses

|   |                             |
|---|-----------------------------|
| Statistical analysis title              | Pearsons's Chi-squared test |
| Comparison groups                       | Active Arm v Placebo arm    |
| Number of subjects included in analysis | 31                          |
| Analysis specification                  | Pre-specified               |
| Analysis type                           | superiority                 |
| P-value                                 | < 0.05                      |
| Method                                  | t-test, 2-sided             |

### Secondary: Hospital admission in the first 5 days post procedure

|                                     |   |
|-------------------------------------|---|
| End point title                     | Hospital admission in the first 5 days post procedure |
| End point description:              |   |
| End point type                      | Secondary   |
| End point timeframe:                |   |
| First 5 days following intervention |   |

| End point values            | Active Arm      | Placebo arm     |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 16              | 15              |  |  |
| Units: Yes/no               | 1               | 0               |  |  |

### Statistical analyses

| Statistical analysis title              | Pearsons's Chi-squared test |
|---|-----------------------------|
| Comparison groups                       | Active Arm v Placebo arm    |
| Number of subjects included in analysis | 31                          |
| Analysis specification                  | Pre-specified               |
| Analysis type                           | superiority                 |
| P-value                                 | < 0.05                      |
| Method                                  | t-test, 2-sided             |

### Secondary: Acute urinary retention in the first 5 days post procedure

|                                     |  |
|-------------------------------------|--|
| End point title                     | Acute urinary retention in the first 5 days post procedure |
| End point description:              |  |
| End point type                      | Secondary  |
| End point timeframe:                |  |
| First 5 days following intervention |  |

| End point values            | Active Arm      | Placebo arm     |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 16              | 15              |  |  |
| Units: Yes/no               | 0               | 2               |  |  |

### Statistical analyses

| Statistical analysis title              | Pearsons's Chi-squared test |
|---|-----------------------------|
| Comparison groups                       | Active Arm v Placebo arm    |
| Number of subjects included in analysis | 31                          |
| Analysis specification                  | Pre-specified               |
| Analysis type                           | superiority                 |
| P-value                                 | < 0.05                      |
| Method                                  | t-test, 2-sided             |

**Secondary: IPSS score at 1 month post procedure**

|                 |                                      |
|-----------------|--------------------------------------|
| End point title | IPSS score at 1 month post procedure |
|-----------------|--------------------------------------|

End point description:

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

1 month post procedure

| End point values                     | Active Arm      | Placebo arm     |  |  |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type                   | Reporting group | Reporting group |  |  |
| Number of subjects analysed          | 16              | 15              |  |  |
| Units: Points                        |                 |                 |  |  |
| arithmetic mean (standard deviation) | 13.3 (± 9.3)    | 13.9 (± 4.9)    |  |  |

**Statistical analyses**

|                            |                    |
|----------------------------|--------------------|
| Statistical analysis title | Independent t-test |
|----------------------------|--------------------|

|                   |                          |
|-------------------|--------------------------|
| Comparison groups | Active Arm v Placebo arm |
|-------------------|--------------------------|

|   |    |
|---|----|
| Number of subjects included in analysis | 31 |
|---|----|

|                        |               |
|------------------------|---------------|
| Analysis specification | Pre-specified |
|------------------------|---------------|

|               |             |
|---------------|-------------|
| Analysis type | superiority |
|---------------|-------------|

|         |        |
|---------|--------|
| P-value | < 0.05 |
|---------|--------|

|        |                 |
|--------|-----------------|
| Method | t-test, 2-sided |
|--------|-----------------|

|                     |  |
|---------------------|--|
| Confidence interval |  |
|---------------------|--|

**Secondary: IPSS score at 3 months post procedure**

|                 |                                       |
|-----------------|---------------------------------------|
| End point title | IPSS score at 3 months post procedure |
|-----------------|---------------------------------------|

End point description:

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

1 month post procedure

| End point values                     | Active Arm      | Placebo arm     |  |  |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type                   | Reporting group | Reporting group |  |  |
| Number of subjects analysed          | 16              | 15              |  |  |
| Units: Points                        |                 |                 |  |  |
| arithmetic mean (standard deviation) | 11.1 (± 9.2)    | 10.9 (± 7.4)    |  |  |



### Statistical analyses

|   |                          |
|---|--------------------------|
| <b>Statistical analysis title</b>       | Independent t-test       |
| Comparison groups                       | Active Arm v Placebo arm |
| Number of subjects included in analysis | 31                       |
| Analysis specification                  | Pre-specified            |
| Analysis type                           | superiority              |
| P-value                                 | < 0.05                   |
| Method                                  | t-test, 2-sided          |
| Confidence interval                     |                          |

### Secondary: IPSS score at 6 months post procedure

|                         |                                       |
|-------------------------|---------------------------------------|
| End point title         | IPSS score at 6 months post procedure |
| End point description:  |                                       |
| End point type          | Secondary                             |
| End point timeframe:    |                                       |
| 6 months post procedure |                                       |

|                                      |                 |                 |  |  |
|--------------------------------------|-----------------|-----------------|--|--|
| <b>End point values</b>              | Active Arm      | Placebo arm     |  |  |
| Subject group type                   | Reporting group | Reporting group |  |  |
| Number of subjects analysed          | 16              | 15              |  |  |
| Units: Points                        |                 |                 |  |  |
| arithmetic mean (standard deviation) | 14.2 (± 8.1)    | 12.3 (± 6.2)    |  |  |

### Statistical analyses

|   |                          |
|---|--------------------------|
| <b>Statistical analysis title</b>       | Independent t-test       |
| Comparison groups                       | Active Arm v Placebo arm |
| Number of subjects included in analysis | 31                       |
| Analysis specification                  | Pre-specified            |
| Analysis type                           | superiority              |
| P-value                                 | < 0.05                   |
| Method                                  | t-test, 2-sided          |

**Secondary: International Index of Erectile Function (IIEF) score at 1 month post procedure**

|                 |   |
|-----------------|---|
| End point title | International Index of Erectile Function (IIEF) score at 1 month post procedure |
|-----------------|---|

|                        |
|------------------------|
| End point description: |
|------------------------|

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

|                        |
|------------------------|
| End point timeframe:   |
| 1 month post procedure |

| End point values                     | Active Arm        | Placebo arm       |  |  |
|--------------------------------------|-------------------|-------------------|--|--|
| Subject group type                   | Reporting group   | Reporting group   |  |  |
| Number of subjects analysed          | 16                | 15                |  |  |
| Units: Points                        |                   |                   |  |  |
| arithmetic mean (standard deviation) | 15.4 ( $\pm$ 6.3) | 16.4 ( $\pm$ 6.0) |  |  |

**Statistical analyses**

|                                   |                    |
|-----------------------------------|--------------------|
| <b>Statistical analysis title</b> | Independent t-test |
|-----------------------------------|--------------------|

|                   |                          |
|-------------------|--------------------------|
| Comparison groups | Active Arm v Placebo arm |
|-------------------|--------------------------|

|   |    |
|---|----|
| Number of subjects included in analysis | 31 |
|---|----|

|                        |               |
|------------------------|---------------|
| Analysis specification | Pre-specified |
|------------------------|---------------|

|               |             |
|---------------|-------------|
| Analysis type | superiority |
|---------------|-------------|

|         |        |
|---------|--------|
| P-value | < 0.05 |
|---------|--------|

|        |                 |
|--------|-----------------|
| Method | t-test, 2-sided |
|--------|-----------------|

|                     |
|---------------------|
| Confidence interval |
|---------------------|

**Secondary: IPSS score at 3 months post procedure**

|                 |                                       |
|-----------------|---------------------------------------|
| End point title | IPSS score at 3 months post procedure |
|-----------------|---------------------------------------|

|                        |
|------------------------|
| End point description: |
|------------------------|

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

|                         |
|-------------------------|
| End point timeframe:    |
| 3 months post procedure |

| End point values                     | Active Arm      | Placebo arm     |  |  |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type                   | Reporting group | Reporting group |  |  |
| Number of subjects analysed          | 16              | 15              |  |  |
| Units: Points                        |                 |                 |  |  |
| arithmetic mean (standard deviation) | 16.5 (± 6.4)    | 16.6 (± 6.9)    |  |  |

### Statistical analyses

| Statistical analysis title              | Independent t-test       |
|---|--------------------------|
| Comparison groups                       | Active Arm v Placebo arm |
| Number of subjects included in analysis | 31                       |
| Analysis specification                  | Pre-specified            |
| Analysis type                           | superiority              |
| P-value                                 | < 0.05                   |
| Method                                  | t-test, 2-sided          |
| Confidence interval                     |                          |

### Secondary: IPSS score at 6 months post procedure

|                         |                                       |
|-------------------------|---------------------------------------|
| End point title         | IPSS score at 6 months post procedure |
| End point description:  |                                       |
| End point type          | Secondary                             |
| End point timeframe:    |                                       |
| 6 months post procedure |                                       |

| End point values                     | Active Arm      | Placebo arm     |  |  |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type                   | Reporting group | Reporting group |  |  |
| Number of subjects analysed          | 16              | 15              |  |  |
| Units: Points                        |                 |                 |  |  |
| arithmetic mean (standard deviation) | 15.4 (± 7.8)    | 15.7 (± 6.9)    |  |  |

### Statistical analyses

| Statistical analysis title | Independent t-test       |
|----------------------------|--------------------------|
| Comparison groups          | Active Arm v Placebo arm |

|   |                 |
|---|-----------------|
| Number of subjects included in analysis | 31              |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority     |
| P-value                                 | < 0.05          |
| Method                                  | t-test, 2-sided |
| Confidence interval                     |                 |

### Secondary: Mean urinary flow at 3 months post procedure

|                         |  |
|-------------------------|--|
| End point title         | Mean urinary flow at 3 months post procedure |
| End point description:  |  |
| End point type          | Secondary                                    |
| End point timeframe:    |  |
| 3 months post procedure |  |

| End point values                     | Active Arm      | Placebo arm     |  |  |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type                   | Reporting group | Reporting group |  |  |
| Number of subjects analysed          | 16              | 15              |  |  |
| Units: Milliliters per second        |                 |                 |  |  |
| arithmetic mean (standard deviation) | 4.8 (± 2.9)     | 4.7 (± 2.1)     |  |  |

### Statistical analyses

|   |                          |
|---|--------------------------|
| Statistical analysis title              | Independent t-test       |
| Comparison groups                       | Active Arm v Placebo arm |
| Number of subjects included in analysis | 31                       |
| Analysis specification                  | Pre-specified            |
| Analysis type                           | superiority              |
| P-value                                 | < 0.05                   |
| Method                                  | t-test, 2-sided          |
| Confidence interval                     |                          |

### Secondary: Mean urinary flow at 6 months post procedure

|                         |  |
|-------------------------|--|
| End point title         | Mean urinary flow at 6 months post procedure |
| End point description:  |  |
| End point type          | Secondary                                    |
| End point timeframe:    |  |
| 6 months post procedure |  |

| <b>End point values</b>              | Active Arm      | Placebo arm     |  |  |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type                   | Reporting group | Reporting group |  |  |
| Number of subjects analysed          | 16              | 15              |  |  |
| Units: Milliliters per second        |                 |                 |  |  |
| arithmetic mean (standard deviation) | 4.1 (± 1.7)     | 4.7 (± 2.6)     |  |  |

### Statistical analyses

| <b>Statistical analysis title</b>       | Independent t-test       |
|---|--------------------------|
| Comparison groups                       | Active Arm v Placebo arm |
| Number of subjects included in analysis | 31                       |
| Analysis specification                  | Pre-specified            |
| Analysis type                           | superiority              |
| P-value                                 | < 0.05                   |
| Method                                  | t-test, 2-sided          |
| Confidence interval                     |                          |

### Secondary: Maximum urinary flow at 3 months post procedure

|                         |   |
|-------------------------|---|
| End point title         | Maximum urinary flow at 3 months post procedure |
| End point description:  |   |
| End point type          | Secondary                                       |
| End point timeframe:    |   |
| 3 months post procedure |   |

| <b>End point values</b>              | Active Arm      | Placebo arm     |  |  |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type                   | Reporting group | Reporting group |  |  |
| Number of subjects analysed          | 16              | 15              |  |  |
| Units: Milliliters per second        |                 |                 |  |  |
| arithmetic mean (standard deviation) | 12.0 (± 5.9)    | 11.9 (± 6.0)    |  |  |

### Statistical analyses

| <b>Statistical analysis title</b> | Independent t-test       |
|-----------------------------------|--------------------------|
| Comparison groups                 | Active Arm v Placebo arm |

|   |                 |
|---|-----------------|
| Number of subjects included in analysis | 31              |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority     |
| P-value                                 | < 0.05          |
| Method                                  | t-test, 2-sided |
| Confidence interval                     |                 |

### Secondary: Maximum urinary flow at 6 months post procedure

|                         |   |
|-------------------------|---|
| End point title         | Maximum urinary flow at 6 months post procedure |
| End point description:  |   |
| End point type          | Secondary                                       |
| End point timeframe:    |   |
| 6 months post procedure |   |

| End point values                     | Active Arm      | Placebo arm     |  |  |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type                   | Reporting group | Reporting group |  |  |
| Number of subjects analysed          | 16              | 15              |  |  |
| Units: Milliliters per second        |                 |                 |  |  |
| arithmetic mean (standard deviation) | 11.3 (± 5.8)    | 11.6 (± 6.6)    |  |  |

### Statistical analyses

|   |                          |
|---|--------------------------|
| <b>Statistical analysis title</b>       | Independent t-test       |
| Comparison groups                       | Active Arm v Placebo arm |
| Number of subjects included in analysis | 31                       |
| Analysis specification                  | Pre-specified            |
| Analysis type                           | superiority              |
| P-value                                 | < 0.05                   |
| Method                                  | t-test, 2-sided          |
| Confidence interval                     |                          |

### Secondary: Prostate volume at 3 months post procedure

|                         |  |
|-------------------------|--|
| End point title         | Prostate volume at 3 months post procedure |
| End point description:  |  |
| End point type          | Secondary                                  |
| End point timeframe:    |  |
| 3 months post procedure |  |

| End point values                     | Active Arm      | Placebo arm     |  |  |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type                   | Reporting group | Reporting group |  |  |
| Number of subjects analysed          | 16              | 15              |  |  |
| Units: Cubic centimeters             |                 |                 |  |  |
| arithmetic mean (standard deviation) | 80 ( $\pm$ 27)  | 89 ( $\pm$ 33)  |  |  |

### Statistical analyses

| Statistical analysis title              | Independent t-test       |
|---|--------------------------|
| Comparison groups                       | Active Arm v Placebo arm |
| Number of subjects included in analysis | 31                       |
| Analysis specification                  | Pre-specified            |
| Analysis type                           | superiority              |
| P-value                                 | < 0.05                   |
| Method                                  | t-test, 2-sided          |
| Confidence interval                     |                          |

### Secondary: Prostate volume at 6 months post procedure

|                         |  |
|-------------------------|--|
| End point title         | Prostate volume at 6 months post procedure |
| End point description:  |  |
| End point type          | Secondary                                  |
| End point timeframe:    |  |
| 6 months post procedure |  |

| End point values                     | Active Arm      | Placebo arm     |  |  |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type                   | Reporting group | Reporting group |  |  |
| Number of subjects analysed          | 16              | 15              |  |  |
| Units: Cubic centimeters             |                 |                 |  |  |
| arithmetic mean (standard deviation) | 76 ( $\pm$ 26)  | 72 ( $\pm$ 18)  |  |  |

### Statistical analyses

| Statistical analysis title | Independent t-test       |
|----------------------------|--------------------------|
| Comparison groups          | Active Arm v Placebo arm |

|   |                 |
|---|-----------------|
| Number of subjects included in analysis | 31              |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority     |
| P-value                                 | < 0.05          |
| Method                                  | t-test, 2-sided |
| Confidence interval                     |                 |

### Secondary: Residual urine at 3 months post procedure

|                         |   |
|-------------------------|---|
| End point title         | Residual urine at 3 months post procedure |
| End point description:  |   |
| End point type          | Secondary                                 |
| End point timeframe:    |   |
| 3 months post procedure |   |

| End point values                      | Active Arm      | Placebo arm     |  |  |
|---------------------------------------|-----------------|-----------------|--|--|
| Subject group type                    | Reporting group | Reporting group |  |  |
| Number of subjects analysed           | 16              | 15              |  |  |
| Units: Milliliters                    |                 |                 |  |  |
| median (inter-quartile range (Q1-Q3)) | 28 (5 to 57)    | 20 (0 to 57)    |  |  |

### Statistical analyses

|   |                          |
|---|--------------------------|
| Statistical analysis title              | Independent t-test       |
| Comparison groups                       | Active Arm v Placebo arm |
| Number of subjects included in analysis | 31                       |
| Analysis specification                  | Pre-specified            |
| Analysis type                           | superiority              |
| P-value                                 | < 0.05                   |
| Method                                  | t-test, 2-sided          |
| Confidence interval                     |                          |

### Secondary: Residual urine at 6 months post procedure

|                         |   |
|-------------------------|---|
| End point title         | Residual urine at 6 months post procedure |
| End point description:  |   |
| End point type          | Secondary                                 |
| End point timeframe:    |   |
| 6 months post procedure |   |



| End point values                      | Active Arm      | Placebo arm     |  |  |
|---------------------------------------|-----------------|-----------------|--|--|
| Subject group type                    | Reporting group | Reporting group |  |  |
| Number of subjects analysed           | 16              | 15              |  |  |
| Units: Milliliters                    |                 |                 |  |  |
| median (inter-quartile range (Q1-Q3)) | 49 (12 to 95)   | 55 (50 to 80)   |  |  |

### Statistical analyses

| Statistical analysis title              | Independent t-test       |
|---|--------------------------|
| Comparison groups                       | Active Arm v Placebo arm |
| Number of subjects included in analysis | 31                       |
| Analysis specification                  | Pre-specified            |
| Analysis type                           | superiority              |
| P-value                                 | < 0.05                   |
| Method                                  | t-test, 2-sided          |
| Confidence interval                     |                          |

### Secondary: Prostate specific antigen (PSA) at 1 month post procedure

|                        |   |
|------------------------|---|
| End point title        | Prostate specific antigen (PSA) at 1 month post procedure |
| End point description: |   |
| End point type         | Secondary   |
| End point timeframe:   |   |
| 1 month post procedure |   |

| End point values                      | Active Arm      | Placebo arm     |  |  |
|---------------------------------------|-----------------|-----------------|--|--|
| Subject group type                    | Reporting group | Reporting group |  |  |
| Number of subjects analysed           | 16              | 15              |  |  |
| Units: Micrograms per litre           |                 |                 |  |  |
| median (inter-quartile range (Q1-Q3)) | 6.1 (5.3 to 10) | 6.4 (5.2 to 10) |  |  |

### Statistical analyses

| Statistical analysis title | Independent t-test       |
|----------------------------|--------------------------|
| Comparison groups          | Active Arm v Placebo arm |

|   |                 |
|---|-----------------|
| Number of subjects included in analysis | 31              |
| Analysis specification                  | Pre-specified   |
| Analysis type                           | superiority     |
| P-value                                 | < 0.05          |
| Method                                  | t-test, 2-sided |
| Confidence interval                     |                 |

### Secondary: Prostate specific antigen (PSA) at 3 months post procedure

|                         |  |
|-------------------------|--|
| End point title         | Prostate specific antigen (PSA) at 3 months post procedure |
| End point description:  |  |
| End point type          | Secondary  |
| End point timeframe:    |  |
| 3 months post procedure |  |

| End point values                      | Active Arm       | Placebo arm      |  |  |
|---------------------------------------|------------------|------------------|--|--|
| Subject group type                    | Reporting group  | Reporting group  |  |  |
| Number of subjects analysed           | 16               | 15               |  |  |
| Units: Micrograms per litre           |                  |                  |  |  |
| median (inter-quartile range (Q1-Q3)) | 5.3 (3.2 to 7.5) | 5.3 (3.9 to 7.3) |  |  |

### Statistical analyses

|   |                          |
|---|--------------------------|
| Statistical analysis title              | Independent t-test       |
| Comparison groups                       | Active Arm v Placebo arm |
| Number of subjects included in analysis | 31                       |
| Analysis specification                  | Pre-specified            |
| Analysis type                           | superiority              |
| P-value                                 | < 0.05                   |
| Method                                  | t-test, 2-sided          |
| Confidence interval                     |                          |

### Secondary: Prostate specific antigen (PSA) at 6 months post procedure

|                         |  |
|-------------------------|--|
| End point title         | Prostate specific antigen (PSA) at 6 months post procedure |
| End point description:  |  |
| End point type          | Secondary  |
| End point timeframe:    |  |
| 6 months post procedure |  |

| <b>End point values</b>               | Active Arm       | Placebo arm      |  |  |
|---------------------------------------|------------------|------------------|--|--|
| Subject group type                    | Reporting group  | Reporting group  |  |  |
| Number of subjects analysed           | 16               | 15               |  |  |
| Units: Micrograms per litre           |                  |                  |  |  |
| median (inter-quartile range (Q1-Q3)) | 5.1 (3.9 to 8.8) | 5.4 (4.5 to 7.9) |  |  |

### Statistical analyses

|   |                          |
|---|--------------------------|
| <b>Statistical analysis title</b>       | Independent t-test       |
| Comparison groups                       | Active Arm v Placebo arm |
| Number of subjects included in analysis | 31                       |
| Analysis specification                  | Pre-specified            |
| Analysis type                           | superiority              |
| P-value                                 | < 0.05                   |
| Method                                  | t-test, 2-sided          |
| Confidence interval                     |                          |

## Adverse events

---

### Adverse events information<sup>[1]</sup>

---

Timeframe for reporting adverse events:

Up to 6 months post intervention

|                 |            |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

---

### Dictionary used

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|                 |        |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

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|                    |      |
|--------------------|------|
| Dictionary version | 26.0 |
|--------------------|------|

---

Frequency threshold for reporting non-serious adverse events: 1 %

---

#### Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: No serious adverse events (SAEs) have been observed or reported. and no non-serious adverse events (AEs) were recorded. The absence of non-serious AEs aligns with the study findings, as no participants reported any conditions meeting the criteria for classification as non-serious adverse events. The study was closely monitored to ensure compliance with regulatory guidelines.

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported

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### Online references

<http://www.ncbi.nlm.nih.gov/pubmed/38233575>