Supplementary Online Content


eAppendix 1. Applied rules by the diagnosis and main endpoint validation committee for the main end point

This supplementary material has been provided by the authors to give readers additional information about their work.

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eAppendix 1. Applied Rules by the Diagnosis and Main Endpoint Validation Committee for the Main End Point

1. The patient detected stone expulsion before day 42.

Case 1: Stone expulsion considered at the date declared by the patient.

2. The patient did not detect stone expulsion before day 42.

2.1. Investigation(s)* performed before day 42 showing stone expulsion.

Case 2: Stone expulsion considered at the date of the first investigation, which did not show the stone anymore.

2.2. First investigation performed after day 42 showing stone expulsion.

Case 3: Patient censored at the date of the last pain relapse or at the date of the last investigation showing the stone or at the date of hospital release (last sifting).

2.3. Last investigation performed before day 42 showing the stone.

Case 4: Patient censored at the date of the last pain relapse or at the date of the last investigation showing the stone.

2.4. Surgery before day 42.

Case 5: Patient censored at the date of surgery.

2.5. Lost to follow-up without investigation after the inclusion.

Case 6: Patient censored at the date of the last pain relapse or at the date of hospital release (last sifting).

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2.6. Last investigation after day 42 showing the stone or surgery after day 42 or spontaneous stone expulsion declared by the patient after day 42.

Case 7: Patient censored at day 42.

* Investigations: plain abdominal radiography and/or spiraled tomodensitometry.

**Appendix 2. Principle of the Triangular Test**

The triangular test uses a sequential plan defined by 2 perpendicular axes. The horizontal axis corresponds to a first statistic $V$, which represents the quantity of information accumulated since the beginning of the trial. The vertical axis corresponds to a second statistic $Z$, which represents the benefit with the experimental treatment as compared with the control. Two straight lines, called the *boundaries of the test*, delineate a continuation region (situated in between these lines) from the regions of nonrejection and of rejection of the null hypothesis. The boundaries intersect, thus defining a closed continuation region with a triangular shape. The equations of the boundaries depend on the values of the benefit to detect and on the type I error and power, as well as on the frequency of the analyses, defined in terms of the number of patients included between 2 analyses. Because this number usually varies at each analysis, the boundaries need to be adjusted concomitantly, thus defining a continuation region with a Christmas tree shape. At each analysis, $Z$ and $V$ are computed

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from all the data collected since the beginning of the study and \( Z \) is plotted against \( V \), thus defining a point on the sequential plan. The consecutive points define a sample path. The trial is continued and new patients are included as long as the sample path remains in the continuation region. A conclusion is reached as soon as the sample path crosses one of the boundaries of the test: if the sample path crosses the upper boundary, the experimental treatment is demonstrated to be significantly superior to the control; if the sample path crosses the lower boundary, the experimental treatment is not significantly different from the control.