Serious Adverse Event Report

Event 14-Jan-2022 - report of 04-Jul-2022 - 14:05 UTC, revision 5

Initial Report Date	19-Jan-2022
Date of this report	04-Jul-2022
Investigator/reporter	Julia Macias
Study Protocol (Id and Title)	H-34 - DELTA Revision study
Site Information	101 - Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP
Patient ID	10
Event onset	14-Jan-2022
Report type	Final
Date of Study Team Aware	14-Jan-2022 08:51
Title of clinical study	H-34 - DELTA Revision study
Name of the healthcare facility	Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP
Name of the Principal Investigator	Jerzy Białecki
Name of the medical device involved	N/A
Components involved	N/A
ID number of study subject	101 - 10
Age	76
Gender	Male
Attribution within the clinical investigation	TreatmentGroup

Adverse Event (diagnosis, if known, or signs/symptoms)	Dyspnoea, fluid collection in lungs
Event narrative	Chronic heart failure exacerbation
Admission date (dd-mmm-yyyy)	30-Dec-2021
Discharge date (dd-mmm-yyyy)	18-Jan-2022
Classification of the adverse event	Hospitalization
Outcome of the event	Recovered 09-Jun-2022
Relevant concomitant drugs and date of administration	Furosemid 40mg 2xday from 14.01.2022.
Detail all possible and suspected causes including relevant medical histor	Chronic heart failure
Current clinical status	Good
Severity	Moderate
Causality: relationship to study medical device	NotRelated
Causality: relationship to study procedure	NotRelated
Expectedness	NA
Action taken	Pharmacological
Was the device permanently removed?	No
Detailed treatment	Farmacological treatment: Furosemid 40mg 2xday from 14.01.2022 to 18.01.2022. With this treatment we got an improvement.
Relevant medical history	None
Relevant medical records	None

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Laboratory Results	None
Imaging Methods (e.g., X-ray, CT-scan)	None
Other (please specify)	None
Submitter	Investigator
Name of submitter	Pawel Bartosz

LimeS CLINICAL DATABASE

Clinical Study: H-34 DELTA Revision study
Patient ID: 101/10
Form: Adverse event

Date	Time	User	Values
04-Jul-2022	14:05:29 (UTC)	Julia Macias (maciasjulia@gmail.com)	- Notes: from **<empty>** to **Delta Revision Cup has been implanted in coupling with a competitor stem, because the stem was well osteointegrated. There was no need to remove to remove it.**
04-Jul-2022	14:04:22 (UTC)	Julia Macias (maciasjulia@gmail.com)	- .ReportType: from **Initial** to **Final**
09-Jun-2022	09:56:06 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- Detailed treatment: from **Farmacological treatment: Furosemid 40mg 2xday from 14.01.2022. With this treatment we got an improvement.** to **Farmacological treatment: Furosemid 40mg 2xday from 14.01.2022 to 18.01.2022. With this treatment we got an improvement.**
09-Jun-2022	09:55:33 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- Name of the medical device involved: from **<empty>** to **<empty>** - Components involved: from **<empty>** to **<empty>** - Outcome of the event: from **Ongoing** to **Recovered** - Outcome / Recovered date: from **<empty>**

			to **09-Jun-2022** - Action taken regarding study device / Other: from **<empty>** to **<empty>** - Detailed treatment: from **<empty>** to **Farmacological treatment: Furosemid 40mg 2xday from 14.01.2022. With this treatment we got an improvement.** - Notes: from **<empty>** to **<empty>**
19-Jan-2022	06:46:08 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	- ReportType: value **Initial** - Initial Report Date: value **19-Jan-2022** - Report Date: value **19-Jan-2022** - Date of Study Team Aware: value **14-Jan-2022** - Time team became aware (24 hr clock): value **08:51:00** - Title of clinical study: value **DELTA Revision study** - Protocol ID: value **H-34** - Name of the healthcare facility: value **Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP** - Name of the Principal Investigator: value **Jerzy Białecki** - Name of the medical device involved: value **<empty>** - IsMedicalDeviceNameNA: value **True**

			- Components involved: value **<empty>** - IsMedicalDeviceComponentsNA: value **True** - ID number of study subject: value **101 - 10** - Age: value **76** - Gender: value **Male** - Attribution within the clinical investigation: value **TreatmentGroup** - Adverse Event (diagnosis, if known, or signs/symptoms): value **Dyspnoea, fluid collection in lungs** - Event narrative: value **Chronic heart failure exacerbation** - Admission date (dd-mmm-yyyy): value **30-Dec-2021** - IsEventInformationAdmissionDateNA: value **False** - Discharge date (dd-mmm-yyyy): value **18-Jan-2022** - IsEventInformationDischargeDateNA: value **False** - Classification of the adverse event: value **Hospitalization** - Outcome of the event: value **Ongoing** - Outcome / Recovered date: value **<empty>** - Outcome / Recovered with sequalae date: value **<empty>** - Outcome / Fatal date: value **<empty>**

			- Relevant concomitant drugs and date of administration: value **Furosemid 40mg 2xday from 14.01.2022.** - Detail all possible and suspected causes including relevant medical history: value **Chronic heart failure** - Current clinical status: value **Good** - Severity: value **Moderate** - Causality: relationship to study medical device: value **NotRelated** - Causality: relationship to study procedure: value **NotRelated** - Expectedness: value **NA** - Action taken: value **Pharmacological** - Was the device permanently removed?: value **False** - If yes, then please specify date of removal surgery: value **<empty>** - Action taken regarding study device / Other: value **<empty>** - Detailed treatment: value **<empty>** - Attachments / Relevant medical history: value **False** - Attachments / Relevant medical records: value **False** - Attachments / Laboratory Results: value **False** - Attachments / Imaging Methods (e.g., X-ray, CT-scan): value **False** - Attachments / Other: value **False**

			- Attachments / Other / Specify: value **<empty>** - Submitter: value **Investigator** - Name of submitter: value **Pawel Bartosz** - Event Onset: value **14-Jan-2022** - Serious Event: value **True** - Notes: value **<empty>**