

Serious Adverse Event Report

Event 14-Jan-2022 - report of 09-Jun-2022 - 09:55 UTC, revision 2

Initial Report Date	19-Jan-2022
Date of this report	09-Jun-2022
Investigator/reporter	Pawel Bartosz
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	Initial
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

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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 history	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. 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

Clinical Study: H-34 DELTA Revision study

Patient ID: 101/10

Form: Adverse event

Date	Time	User	Values
09-Jun-2022	09:55:33 (UTC)	Pawel Bartosz (pbartosz@vp.pl)	<ul style="list-style-type: none"> - 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)	<ul style="list-style-type: none"> - ReportType: value Initial

			<ul style="list-style-type: none"> - 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 Biłdecki - 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):
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			<ul style="list-style-type: none"> value Dyspnoea, fluid collection in lungs - Event narrative: <ul style="list-style-type: none"> value Chronic heart failure exacerbation - Admission date (dd-mmm-yyyy): <ul style="list-style-type: none"> value 30-Dec-2021 - IsEventInformationAdmissionDateNA: <ul style="list-style-type: none"> value False - Discharge date (dd-mmm-yyyy): <ul style="list-style-type: none"> value 18-Jan-2022 - IsEventInformationDischargeDateNA: <ul style="list-style-type: none"> value False - Classification of the adverse event: <ul style="list-style-type: none"> value Hospitalization - Outcome of the event: <ul style="list-style-type: none"> value Ongoing - Outcome / Recovered date: <ul style="list-style-type: none"> value <empty> - Outcome / Recovered with sequelae date: <ul style="list-style-type: none"> value <empty> - Outcome / Fatal date: <ul style="list-style-type: none"> value <empty> - Relevant concomitant drugs and date of administration: <ul style="list-style-type: none"> value Furosemid 40mg 2xday from 14.01.2022. - Detail all possible and suspected causes including relevant medical history: <ul style="list-style-type: none"> value Chronic heart failure - Current clinical status: <ul style="list-style-type: none"> value Good - Severity: <ul style="list-style-type: none"> value Moderate - Causality: relationship to study medical device: <ul style="list-style-type: none"> value NotRelated - Causality: relationship to study procedure: <ul style="list-style-type: none"> value NotRelated - Expectedness:
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			<p>value NA</p> <p>- Action taken: value Pharmacological</p> <p>- Was the device permanently removed?: value False</p> <p>- If yes, then please specify date of removal surgery: value <empty></p> <p>- Action taken regarding study device / Other: value <empty></p> <p>- Detailed treatment: value <empty></p> <p>- Attachments / Relevant medical history: value False</p> <p>- Attachments / Relevant medical records: value False</p> <p>- Attachments / Laboratory Results: value False</p> <p>- Attachments / Imaging Methods (e.g., X-ray, CT-scan): value False</p> <p>- Attachments / Other: value False</p> <p>- Attachments / Other / Specify: value <empty></p> <p>- Submitter: value Investigator</p> <p>- Name of submitter: value Pawel Bartosz</p> <p>- Event Onset: value 14-Jan-2022</p> <p>- Serious Event: value True</p> <p>- Notes: value <empty></p>
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