**FRITS**

**EFFICACY**

**Table : Number and type of antiplatelet medications at 12-month visit (INVESTIGATORS) [ITT - N=143 patients]**

|  | | **FRED / FRED Jr N=91** | **FRED X N=52** | **Total N=143** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Antiplatelet therapy** | N | 91 |  | 91 |
|  | Missing data | 0 |  | 0 |
|  | No treatment | 1 (1.1%) |  | 1 (0.7%) |
|  | Single antiplatelet therapy | 59 (64.8%) | 33 (63.5%) | 92 (64.3%) |
|  | Dual antiplatelet therapy | 29 (31.9%) | 16 (30.8%) | 45 (31.5%) |
|  | Triple antiplatelet therapy | 2 (2.2%) | 3 (5.8%) | 5 (3.5%) |
|  | Between group test |  |  | 0.713 (Fisher) |
|  |  |  |  |  |
| **Single antiplatelet therapy** | N | 59 |  | 59 |
|  | Missing data | 0 |  | 0 |
|  | ASA (Aspirin) | 58 (98.3%) | 33 (100.0%) | 91 (98.9%) |
|  | Ticlagrelor (Brilique) | 1 (1.7%) |  | 1 (1.1%) |
|  |  |  |  |  |
| **Dual antiplatelet therapy** | N | 29 |  | 29 |
|  | Missing data | 0 |  | 0 |
|  | ASA (Aspirin) + Clopidogrel (Plavix) | 23 (79.3%) | 14 (87.5%) | 37 (82.2%) |
|  | ASA (Aspirin) + Prasugrel (Efient) | 3 (10.3%) | 2 (12.5%) | 5 (11.1%) |
|  | ASA (Aspirin) + Ticlagrelor (Brilique) | 2 (6.9%) |  | 2 (4.4%) |
|  | ASA (Aspirin) + Other | 1 (3.4%) |  | 1 (2.2%) |
|  |  |  |  |  |
| **Triple antiplatelet therapy** | N | 2 |  | 2 |
|  | Missing data | 0 |  | 0 |
|  | ASA (Aspirin) + Clopidogrel (Plavix) + Other | 1 (50.0%) | 1 (33.3%) | 2 (40.0%) |
|  | ASA (Aspirin) + Clopidogrel (Plavix) + Prasugrel (Efient) | 1 (50.0%) | 1 (33.3%) | 2 (40.0%) |
|  | ASA (Aspirin) + Prasugrel (Efient) + Ticlagrelor (Brilique) | 0 | 1 (33.3%) | 1 (20.0%) |

**FRITS**

**EFFICACY**

**Table : Listing of patient without antiplatelet medications at 12-month visit (INVESTIGATORS) [ITT - N= 1 patient]**

| **Subject Identifier for the Study** | **Intent-To-Treat (ITT) at procedure** | **Full Analysis Set (FAS)at procedure** | **Per Protocol(PP) at procedure visit** | **Intent-To-Treat (ITT) for safety analysis at 12-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 12-month follow-up visit** | **Full Analysis Set (FAS) at 12-month follow-up visit** | **Per Protocol(PP) at 12-month follow-up visit** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 04-005 | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| 04-005 | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| N = 2 | | | | | | | |

| **Full Analysis Set (FAS) at 6-month follow-up visit** | **Intent-To-Treat (ITT) for safety analysis at 6-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 6-month follow-up visit** | **Per Protocol(PP) at 6-month follow-up visit** | **Age calculated** | **Gender** | **Subgroup device** | **FRED used type** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Yes | Yes | Yes | Yes | 62 | Female | FRED / FRED Jr | FRED |
| Yes | Yes | Yes | Yes | 62 | Female | FRED / FRED Jr | FRED |
| N = 2 | | | | | | | |

| **PROCEDURE DATE** | **all** | **Antiplatelet therapy at the 12-month visit** | **ASA (Aspirin)** | **Clopidogrel (Plavix)** | **Ticlopidine (Ticlid)** | **Prasugrel (Efient)** | **Ticlagrelor (Brilique)** | **Warfarin (Coumadin)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 04/11/2019 | 1 | 0 | . | . | . | . | . | . |
| 04/11/2019 | 1 | 0 | . | . | . | . | . | . |
| N = 2 | | | | | | | | |

| **Acenocoumarol (Mini-Sintrom)** | **Acenocoumarol (Sintrom)** | **Fluindione (Previscan)** | **Other** | **i** | **Antiplatelet therapy** | **Single antiplatelet therapy** | **Dual antiplatelet therapy** | **Triple antiplatelet therapy** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| . | . | . | . | 12 | No treatment | . | . | . |
| . | . | . | . | 12 | No treatment | . | . | . |
| N = 2 | | | | | | | | |

| **Study name** | **Visit num** | **Visit name** | **Premedication/Concomitant therapy** | **DISCHARGE** | **FU 6 MONTHS** | **FU 1 YEAR** | **Antiplatelet therapy number** | **Type** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FRITS | 4 | FU 1 YEAR | No | 07/11/2019 | 04/05/2020 | 09/11/2020 | 1 | Antiplatelet |
| FRITS | 4 | FU 1 YEAR | No | 07/11/2019 | 04/05/2020 | 09/11/2020 | 2 | Antiplatelet |
| N = 2 | | | | | | | | |

| **Treatment name** | **Other treatment specification** | **Daily dose** | **Unit** | **Start date (c)** | **Start date** | **Ongoing** | **End date (c)** | **End date** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ASA (Aspirin) |  | 100 | MG | 30/10/2019 | 30/10/2019 | No | 01/04/2020 | 01/04/2020 |
| Clopidogrel (Plavix) |  | 75 | MG | 30/10/2019 | 30/10/2019 | No | 04/02/2020 | 04/02/2020 |
| N = 2 | | | | | | | | |

**FRITS**

**EFFICACY**

**Table : Listing of patient with other antiplatelet medications at 12-month visit (INVESTIGATORS) [ITT - N= 1 patient]**

| **Subject Identifier for the Study** | **Intent-To-Treat (ITT) at procedure** | **Full Analysis Set (FAS)at procedure** | **Per Protocol(PP) at procedure visit** | **Intent-To-Treat (ITT) for safety analysis at 12-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 12-month follow-up visit** | **Full Analysis Set (FAS) at 12-month follow-up visit** | **Per Protocol(PP) at 12-month follow-up visit** | **Full Analysis Set (FAS) at 6-month follow-up visit** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 07-024 | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| 07-041 | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No |
| 08-008 | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No |
| N = 3 | | | | | | | | |

| **Intent-To-Treat (ITT) for safety analysis at 6-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 6-month follow-up visit** | **Per Protocol(PP) at 6-month follow-up visit** | **Age calculated** | **Gender** | **Subgroup device** | **FRED used type** | **PROCEDURE DATE** | **all** | **Antiplatelet therapy at the 12-month visit** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Yes | No | No | 73 | Female | FRED / FRED Jr | FRED | 22/06/2020 | 1 | 1 |
| No | No | No | 76 | Female | FRED X | FRED X | 12/01/2022 | 1 | 1 |
| No | No | No | 68 | Male | FRED / FRED Jr | FRED | 10/11/2020 | 1 | 1 |
| N = 3 | | | | | | | | | |

| **ASA (Aspirin)** | **Clopidogrel (Plavix)** | **Ticlopidine (Ticlid)** | **Prasugrel (Efient)** | **Ticlagrelor (Brilique)** | **Warfarin (Coumadin)** | **Acenocoumarol (Mini-Sintrom)** | **Acenocoumarol (Sintrom)** | **Fluindione (Previscan)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| . | . | . | . | . | . | . | . | . |
| . | . | . | . | . | . | . | . | . |
| . | . | . | . | . | . | . | . | . |
| N = 3 | | | | | | | | |

| **Other** | **i** | **Antiplatelet therapy** | **Single antiplatelet therapy** | **Dual antiplatelet therapy** | **Triple antiplatelet therapy** | **Study name** | **Visit num** | **Visit name** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 | 12 | Dual antiplatelet therapy | . | ASA (Aspirin) + Other | . | FRITS | 4 | FU 1 YEAR |
| 1 | 12 | Triple antiplatelet therapy | . | . | ASA (Aspirin) + Clopidogrel (Plavix) + Other | FRITS | 4 | FU 1 YEAR |
| 1 | 12 | Triple antiplatelet therapy | . | . | ASA (Aspirin) + Clopidogrel (Plavix) + Other | FRITS | 4 | FU 1 YEAR |
| N = 3 | | | | | | | | |

| **Premedication/Concomitant therapy** | **DISCHARGE** | **FU 6 MONTHS** | **FU 1 YEAR** | **Antiplatelet therapy number** | **Type** | **Treatment name** | **Other treatment specification** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| No | 25/06/2020 | 18/12/2020 | 11/06/2021 | 3 | Antiplatelet | Other | ELIQUIS |
| No | 22/01/2022 | . | 27/02/2023 | 3 | Antiplatelet | Other | EDOXABAN |
| Yes | 16/11/2020 | . | 08/11/2021 | 4 | Antiplatelet | Other | TIROFIBAN |
| N = 3 | | | | | | | |

| **Daily dose** | **Unit** | **Start date (c)** | **Start date** | **Ongoing** | **End date (c)** | **End date** |
| --- | --- | --- | --- | --- | --- | --- |
| 10 | MG | 02/07/2020 | 02/07/2020 | Yes |  | . |
| 60 | MG | 20/01/2022 | 20/01/2022 | Yes |  | . |
| 15 | ML/HR | 06/02/2021 | 06/02/2021 | No | 07/02/2021 | 07/02/2021 |
| N = 3 | | | | | | |

**FRITS**

**EFFICACY**

**Table : Antiplatelet functional test at 12 months visit (INVESTIGATORS) [ITT - N=143 patients]**

|  | | **FRED / FRED Jr N=91** | **FRED X N=52** | **Total N=143** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Antiplatelet functional test performed** | N | 91 |  | 91 |
|  | Missing data | 0 |  | 0 |
|  | No | 6 (6.6%) | 4 (7.7%) | 10 (7.0%) |
|  | Yes | 85 (93.4%) | 48 (92.3%) | 133 (93.0%) |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Antiplatelet functional test results** | N | 85 |  | 85 |
|  | Missing data | 0 |  | 0 |
|  | No resistance | 76 (89.4%) | 45 (93.8%) | 121 (91.0%) |
|  | Aspirin resistance | 1 (1.2%) |  | 1 (0.8%) |
|  | Plavix resistance | 8 (9.4%) | 3 (6.3%) | 11 (8.3%) |
|  | Between group test |  |  | 0.837 (Fisher) |
|  |  |  |  |  |
| **Action undertaken** | N | 9 |  | 9 |
|  | Missing data | 0 |  | 0 |
|  | Change in antiplatelet therapy | 9 (100.0%) | 3 (100.0%) | 12 (100.0%) |

**FRITS**

**EFFICACY**

**Table : Number and type of antiplatelet medications at 12-month visit (INVESTIGATORS) [FAS - N=130 patients]**

|  | | **FRED / FRED Jr N=82** | **FRED X N=48** | **Total N=130** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Antiplatelet therapy** | N | 82 |  | 82 |
|  | Missing data | 0 |  | 0 |
|  | No treatment | 1 (1.2%) |  | 1 (0.8%) |
|  | Single antiplatelet therapy | 55 (67.1%) | 29 (60.4%) | 84 (64.6%) |
|  | Dual antiplatelet therapy | 25 (30.5%) | 16 (33.3%) | 41 (31.5%) |
|  | Triple antiplatelet therapy | 1 (1.2%) | 3 (6.3%) | 4 (3.1%) |
|  | Between group test |  |  | 0.352 (Fisher) |
|  |  |  |  |  |
| **Single antiplatelet therapy** | N | 55 |  | 55 |
|  | Missing data | 0 |  | 0 |
|  | ASA (Aspirin) | 54 (98.2%) | 29 (100.0%) | 83 (98.8%) |
|  | Ticlagrelor (Brilique) | 1 (1.8%) |  | 1 (1.2%) |
|  |  |  |  |  |
| **Dual antiplatelet therapy** | N | 25 |  | 25 |
|  | Missing data | 0 |  | 0 |
|  | ASA (Aspirin) + Clopidogrel (Plavix) | 22 (88.0%) | 14 (87.5%) | 36 (87.8%) |
|  | ASA (Aspirin) + Prasugrel (Efient) | 1 (4.0%) | 2 (12.5%) | 3 (7.3%) |
|  | ASA (Aspirin) + Ticlagrelor (Brilique) | 1 (4.0%) |  | 1 (2.4%) |
|  | ASA (Aspirin) + Other | 1 (4.0%) |  | 1 (2.4%) |
|  |  |  |  |  |
| **Triple antiplatelet therapy** | N | 1 |  | 1 |
|  | Missing data | 0 |  | 0 |
|  | ASA (Aspirin) + Clopidogrel (Plavix) + Other | 1 (100.0%) | 1 (33.3%) | 2 (50.0%) |
|  | ASA (Aspirin) + Clopidogrel (Plavix) + Prasugrel (Efient) | 0 | 1 (33.3%) | 1 (25.0%) |
|  | ASA (Aspirin) + Prasugrel (Efient) + Ticlagrelor (Brilique) | 0 | 1 (33.3%) | 1 (25.0%) |

**FRITS**

**EFFICACY**

**Table : Listing of patient without antiplatelet medications at 12-month visit (INVESTIGATORS) [FAS - N= 1 patient]**

| **Subject Identifier for the Study** | **Intent-To-Treat (ITT) at procedure** | **Full Analysis Set (FAS)at procedure** | **Per Protocol(PP) at procedure visit** | **Intent-To-Treat (ITT) for safety analysis at 12-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 12-month follow-up visit** | **Full Analysis Set (FAS) at 12-month follow-up visit** | **Per Protocol(PP) at 12-month follow-up visit** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 04-005 | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| 04-005 | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| N = 2 | | | | | | | |

| **Full Analysis Set (FAS) at 6-month follow-up visit** | **Intent-To-Treat (ITT) for safety analysis at 6-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 6-month follow-up visit** | **Per Protocol(PP) at 6-month follow-up visit** | **Age calculated** | **Gender** | **Subgroup device** | **FRED used type** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Yes | Yes | Yes | Yes | 62 | Female | FRED / FRED Jr | FRED |
| Yes | Yes | Yes | Yes | 62 | Female | FRED / FRED Jr | FRED |
| N = 2 | | | | | | | |

| **PROCEDURE DATE** | **all** | **Antiplatelet therapy at the 12-month visit** | **ASA (Aspirin)** | **Clopidogrel (Plavix)** | **Ticlopidine (Ticlid)** | **Prasugrel (Efient)** | **Ticlagrelor (Brilique)** | **Warfarin (Coumadin)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 04/11/2019 | 1 | 0 | . | . | . | . | . | . |
| 04/11/2019 | 1 | 0 | . | . | . | . | . | . |
| N = 2 | | | | | | | | |

| **Acenocoumarol (Mini-Sintrom)** | **Acenocoumarol (Sintrom)** | **Fluindione (Previscan)** | **Other** | **i** | **Antiplatelet therapy** | **Single antiplatelet therapy** | **Dual antiplatelet therapy** | **Triple antiplatelet therapy** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| . | . | . | . | 12 | No treatment | . | . | . |
| . | . | . | . | 12 | No treatment | . | . | . |
| N = 2 | | | | | | | | |

| **Study name** | **Visit num** | **Visit name** | **Premedication/Concomitant therapy** | **DISCHARGE** | **FU 6 MONTHS** | **FU 1 YEAR** | **Antiplatelet therapy number** | **Type** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FRITS | 4 | FU 1 YEAR | No | 07/11/2019 | 04/05/2020 | 09/11/2020 | 1 | Antiplatelet |
| FRITS | 4 | FU 1 YEAR | No | 07/11/2019 | 04/05/2020 | 09/11/2020 | 2 | Antiplatelet |
| N = 2 | | | | | | | | |

| **Treatment name** | **Other treatment specification** | **Daily dose** | **Unit** | **Start date (c)** | **Start date** | **Ongoing** | **End date (c)** | **End date** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ASA (Aspirin) |  | 100 | MG | 30/10/2019 | 30/10/2019 | No | 01/04/2020 | 01/04/2020 |
| Clopidogrel (Plavix) |  | 75 | MG | 30/10/2019 | 30/10/2019 | No | 04/02/2020 | 04/02/2020 |
| N = 2 | | | | | | | | |

**FRITS**

**EFFICACY**

**Table : Listing of patient with other antiplatelet medications at 12-month visit [FAS - N= 1 patient]**

| **Subject Identifier for the Study** | **Intent-To-Treat (ITT) at procedure** | **Full Analysis Set (FAS)at procedure** | **Per Protocol(PP) at procedure visit** | **Intent-To-Treat (ITT) for safety analysis at 12-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 12-month follow-up visit** | **Full Analysis Set (FAS) at 12-month follow-up visit** | **Per Protocol(PP) at 12-month follow-up visit** | **Full Analysis Set (FAS) at 6-month follow-up visit** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 07-024 | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| 07-041 | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No |
| 08-008 | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No |
| N = 3 | | | | | | | | |

| **Intent-To-Treat (ITT) for safety analysis at 6-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 6-month follow-up visit** | **Per Protocol(PP) at 6-month follow-up visit** | **Age calculated** | **Gender** | **Subgroup device** | **FRED used type** | **PROCEDURE DATE** | **all** | **Antiplatelet therapy at the 12-month visit** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Yes | No | No | 73 | Female | FRED / FRED Jr | FRED | 22/06/2020 | 1 | 1 |
| No | No | No | 76 | Female | FRED X | FRED X | 12/01/2022 | 1 | 1 |
| No | No | No | 68 | Male | FRED / FRED Jr | FRED | 10/11/2020 | 1 | 1 |
| N = 3 | | | | | | | | | |

| **ASA (Aspirin)** | **Clopidogrel (Plavix)** | **Ticlopidine (Ticlid)** | **Prasugrel (Efient)** | **Ticlagrelor (Brilique)** | **Warfarin (Coumadin)** | **Acenocoumarol (Mini-Sintrom)** | **Acenocoumarol (Sintrom)** | **Fluindione (Previscan)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| . | . | . | . | . | . | . | . | . |
| . | . | . | . | . | . | . | . | . |
| . | . | . | . | . | . | . | . | . |
| N = 3 | | | | | | | | |

| **Other** | **i** | **Antiplatelet therapy** | **Single antiplatelet therapy** | **Dual antiplatelet therapy** | **Triple antiplatelet therapy** | **Study name** | **Visit num** | **Visit name** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 | 12 | Dual antiplatelet therapy | . | ASA (Aspirin) + Other | . | FRITS | 4 | FU 1 YEAR |
| 1 | 12 | Triple antiplatelet therapy | . | . | ASA (Aspirin) + Clopidogrel (Plavix) + Other | FRITS | 4 | FU 1 YEAR |
| 1 | 12 | Triple antiplatelet therapy | . | . | ASA (Aspirin) + Clopidogrel (Plavix) + Other | FRITS | 4 | FU 1 YEAR |
| N = 3 | | | | | | | | |

| **Premedication/Concomitant therapy** | **DISCHARGE** | **FU 6 MONTHS** | **FU 1 YEAR** | **Antiplatelet therapy number** | **Type** | **Treatment name** | **Other treatment specification** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| No | 25/06/2020 | 18/12/2020 | 11/06/2021 | 3 | Antiplatelet | Other | ELIQUIS |
| No | 22/01/2022 | . | 27/02/2023 | 3 | Antiplatelet | Other | EDOXABAN |
| Yes | 16/11/2020 | . | 08/11/2021 | 4 | Antiplatelet | Other | TIROFIBAN |
| N = 3 | | | | | | | |

| **Daily dose** | **Unit** | **Start date (c)** | **Start date** | **Ongoing** | **End date (c)** | **End date** |
| --- | --- | --- | --- | --- | --- | --- |
| 10 | MG | 02/07/2020 | 02/07/2020 | Yes |  | . |
| 60 | MG | 20/01/2022 | 20/01/2022 | Yes |  | . |
| 15 | ML/HR | 06/02/2021 | 06/02/2021 | No | 07/02/2021 | 07/02/2021 |
| N = 3 | | | | | | |

**FRITS**

**EFFICACY**

**Table : Antiplatelet functional test at 12 months visit (INVESTIGATORS) [FAS - N=130 patients]**

|  | | **FRED / FRED Jr N=82** | **FRED X N=48** | **Total N=130** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Antiplatelet functional test performed** | N | 82 |  | 82 |
|  | Missing data | 0 |  | 0 |
|  | No | 6 (7.3%) | 3 (6.3%) | 9 (6.9%) |
|  | Yes | 76 (92.7%) | 45 (93.8%) | 121 (93.1%) |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Antiplatelet functional test results** | N | 76 |  | 76 |
|  | Missing data | 0 |  | 0 |
|  | No resistance | 71 (93.4%) | 42 (93.3%) | 113 (93.4%) |
|  | Aspirin resistance | 1 (1.3%) |  | 1 (0.8%) |
|  | Plavix resistance | 4 (5.3%) | 3 (6.7%) | 7 (5.8%) |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Action undertaken** | N | 5 |  | 5 |
|  | Missing data | 0 |  | 0 |
|  | Change in antiplatelet therapy | 5 (100.0%) | 3 (100.0%) | 8 (100.0%) |

**FRITS**

**EFFICACY**

**Table : Number and type of antiplatelet medications at 12-month visit (INVESTIGATORS) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Antiplatelet therapy** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No treatment | 1 (1.3%) |  | 1 (0.8%) |
|  | Single antiplatelet therapy | 54 (68.4%) | 28 (62.2%) | 82 (66.1%) |
|  | Dual antiplatelet therapy | 23 (29.1%) | 14 (31.1%) | 37 (29.8%) |
|  | Triple antiplatelet therapy | 1 (1.3%) | 3 (6.7%) | 4 (3.2%) |
|  | Between group test |  |  | 0.346 (Fisher) |
|  |  |  |  |  |
| **Single antiplatelet therapy** | N | 54 |  | 54 |
|  | Missing data | 0 |  | 0 |
|  | ASA (Aspirin) | 53 (98.1%) | 28 (100.0%) | 81 (98.8%) |
|  | Ticlagrelor (Brilique) | 1 (1.9%) |  | 1 (1.2%) |
|  |  |  |  |  |
| **Dual antiplatelet therapy** | N | 23 |  | 23 |
|  | Missing data | 0 |  | 0 |
|  | ASA (Aspirin) + Clopidogrel (Plavix) | 20 (87.0%) | 12 (85.7%) | 32 (86.5%) |
|  | ASA (Aspirin) + Prasugrel (Efient) | 1 (4.3%) | 2 (14.3%) | 3 (8.1%) |
|  | ASA (Aspirin) + Ticlagrelor (Brilique) | 1 (4.3%) |  | 1 (2.7%) |
|  | ASA (Aspirin) + Other | 1 (4.3%) |  | 1 (2.7%) |
|  |  |  |  |  |
| **Triple antiplatelet therapy** | N | 1 |  | 1 |
|  | Missing data | 0 |  | 0 |
|  | ASA (Aspirin) + Clopidogrel (Plavix) + Other | 1 (100.0%) | 1 (33.3%) | 2 (50.0%) |
|  | ASA (Aspirin) + Clopidogrel (Plavix) + Prasugrel (Efient) | 0 | 1 (33.3%) | 1 (25.0%) |
|  | ASA (Aspirin) + Prasugrel (Efient) + Ticlagrelor (Brilique) | 0 | 1 (33.3%) | 1 (25.0%) |

**FRITS**

**EFFICACY**

**Table : Listing of patient without antiplatelet medications at 12-month visit (INVESTIGATORS) [PP - N= 1 patient]**

| **Subject Identifier for the Study** | **Intent-To-Treat (ITT) at procedure** | **Full Analysis Set (FAS)at procedure** | **Per Protocol(PP) at procedure visit** | **Intent-To-Treat (ITT) for safety analysis at 12-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 12-month follow-up visit** | **Full Analysis Set (FAS) at 12-month follow-up visit** | **Per Protocol(PP) at 12-month follow-up visit** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 04-005 | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| 04-005 | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| N = 2 | | | | | | | |

| **Full Analysis Set (FAS) at 6-month follow-up visit** | **Intent-To-Treat (ITT) for safety analysis at 6-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 6-month follow-up visit** | **Per Protocol(PP) at 6-month follow-up visit** | **Age calculated** | **Gender** | **Subgroup device** | **FRED used type** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Yes | Yes | Yes | Yes | 62 | Female | FRED / FRED Jr | FRED |
| Yes | Yes | Yes | Yes | 62 | Female | FRED / FRED Jr | FRED |
| N = 2 | | | | | | | |

| **PROCEDURE DATE** | **all** | **Antiplatelet therapy at the 12-month visit** | **ASA (Aspirin)** | **Clopidogrel (Plavix)** | **Ticlopidine (Ticlid)** | **Prasugrel (Efient)** | **Ticlagrelor (Brilique)** | **Warfarin (Coumadin)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 04/11/2019 | 1 | 0 | . | . | . | . | . | . |
| 04/11/2019 | 1 | 0 | . | . | . | . | . | . |
| N = 2 | | | | | | | | |

| **Acenocoumarol (Mini-Sintrom)** | **Acenocoumarol (Sintrom)** | **Fluindione (Previscan)** | **Other** | **i** | **Antiplatelet therapy** | **Single antiplatelet therapy** | **Dual antiplatelet therapy** | **Triple antiplatelet therapy** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| . | . | . | . | 12 | No treatment | . | . | . |
| . | . | . | . | 12 | No treatment | . | . | . |
| N = 2 | | | | | | | | |

| **Study name** | **Visit num** | **Visit name** | **Premedication/Concomitant therapy** | **DISCHARGE** | **FU 6 MONTHS** | **FU 1 YEAR** | **Antiplatelet therapy number** | **Type** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FRITS | 4 | FU 1 YEAR | No | 07/11/2019 | 04/05/2020 | 09/11/2020 | 1 | Antiplatelet |
| FRITS | 4 | FU 1 YEAR | No | 07/11/2019 | 04/05/2020 | 09/11/2020 | 2 | Antiplatelet |
| N = 2 | | | | | | | | |

| **Treatment name** | **Other treatment specification** | **Daily dose** | **Unit** | **Start date (c)** | **Start date** | **Ongoing** | **End date (c)** | **End date** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ASA (Aspirin) |  | 100 | MG | 30/10/2019 | 30/10/2019 | No | 01/04/2020 | 01/04/2020 |
| Clopidogrel (Plavix) |  | 75 | MG | 30/10/2019 | 30/10/2019 | No | 04/02/2020 | 04/02/2020 |
| N = 2 | | | | | | | | |

**FRITS**

**EFFICACY**

**Table : Listing of patient with other antiplatelet medications at 12-month visit [PP - N= 1 patient]**

| **Subject Identifier for the Study** | **Intent-To-Treat (ITT) at procedure** | **Full Analysis Set (FAS)at procedure** | **Per Protocol(PP) at procedure visit** | **Intent-To-Treat (ITT) for safety analysis at 12-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 12-month follow-up visit** | **Full Analysis Set (FAS) at 12-month follow-up visit** | **Per Protocol(PP) at 12-month follow-up visit** | **Full Analysis Set (FAS) at 6-month follow-up visit** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 07-024 | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| 07-041 | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No |
| 08-008 | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No |
| N = 3 | | | | | | | | |

| **Intent-To-Treat (ITT) for safety analysis at 6-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 6-month follow-up visit** | **Per Protocol(PP) at 6-month follow-up visit** | **Age calculated** | **Gender** | **Subgroup device** | **FRED used type** | **PROCEDURE DATE** | **all** | **Antiplatelet therapy at the 12-month visit** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Yes | No | No | 73 | Female | FRED / FRED Jr | FRED | 22/06/2020 | 1 | 1 |
| No | No | No | 76 | Female | FRED X | FRED X | 12/01/2022 | 1 | 1 |
| No | No | No | 68 | Male | FRED / FRED Jr | FRED | 10/11/2020 | 1 | 1 |
| N = 3 | | | | | | | | | |

| **ASA (Aspirin)** | **Clopidogrel (Plavix)** | **Ticlopidine (Ticlid)** | **Prasugrel (Efient)** | **Ticlagrelor (Brilique)** | **Warfarin (Coumadin)** | **Acenocoumarol (Mini-Sintrom)** | **Acenocoumarol (Sintrom)** | **Fluindione (Previscan)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| . | . | . | . | . | . | . | . | . |
| . | . | . | . | . | . | . | . | . |
| . | . | . | . | . | . | . | . | . |
| N = 3 | | | | | | | | |

| **Other** | **i** | **Antiplatelet therapy** | **Single antiplatelet therapy** | **Dual antiplatelet therapy** | **Triple antiplatelet therapy** | **Study name** | **Visit num** | **Visit name** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 | 12 | Dual antiplatelet therapy | . | ASA (Aspirin) + Other | . | FRITS | 4 | FU 1 YEAR |
| 1 | 12 | Triple antiplatelet therapy | . | . | ASA (Aspirin) + Clopidogrel (Plavix) + Other | FRITS | 4 | FU 1 YEAR |
| 1 | 12 | Triple antiplatelet therapy | . | . | ASA (Aspirin) + Clopidogrel (Plavix) + Other | FRITS | 4 | FU 1 YEAR |
| N = 3 | | | | | | | | |

| **Premedication/Concomitant therapy** | **DISCHARGE** | **FU 6 MONTHS** | **FU 1 YEAR** | **Antiplatelet therapy number** | **Type** | **Treatment name** | **Other treatment specification** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| No | 25/06/2020 | 18/12/2020 | 11/06/2021 | 3 | Antiplatelet | Other | ELIQUIS |
| No | 22/01/2022 | . | 27/02/2023 | 3 | Antiplatelet | Other | EDOXABAN |
| Yes | 16/11/2020 | . | 08/11/2021 | 4 | Antiplatelet | Other | TIROFIBAN |
| N = 3 | | | | | | | |

| **Daily dose** | **Unit** | **Start date (c)** | **Start date** | **Ongoing** | **End date (c)** | **End date** |
| --- | --- | --- | --- | --- | --- | --- |
| 10 | MG | 02/07/2020 | 02/07/2020 | Yes |  | . |
| 60 | MG | 20/01/2022 | 20/01/2022 | Yes |  | . |
| 15 | ML/HR | 06/02/2021 | 06/02/2021 | No | 07/02/2021 | 07/02/2021 |
| N = 3 | | | | | | |

**FRITS**

**EFFICACY**

**Table : Antiplatelet functional test at 12 months visit (INVESTIGATORS) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Antiplatelet functional test performed** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 6 (7.6%) | 2 (4.4%) | 8 (6.5%) |
|  | Yes | 73 (92.4%) | 43 (95.6%) | 116 (93.5%) |
|  | Between group test |  |  | 0.710 (Fisher) |
|  |  |  |  |  |
| **Antiplatelet functional test results** | N | 73 |  | 73 |
|  | Missing data | 0 |  | 0 |
|  | No resistance | 68 (93.2%) | 40 (93.0%) | 108 (93.1%) |
|  | Aspirin resistance | 1 (1.4%) |  | 1 (0.9%) |
|  | Plavix resistance | 4 (5.5%) | 3 (7.0%) | 7 (6.0%) |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Action undertaken** | N | 5 |  | 5 |
|  | Missing data | 0 |  | 0 |
|  | Change in antiplatelet therapy | 5 (100.0%) | 3 (100.0%) | 8 (100.0%) |