



Annual report 2014 (regarding July 2013 – August 2014)

| | Description |
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| 1. Date | August 20, 2014 |
| 2. Institute and address | Erasmus MC Cancer Institute Department of Medical Oncology 's Gravendijkwal 230, 3015 CE Rotterdam |
| 3. Projectleader(s) | Prof. dr. Stefan Sleijfer |
| 4. E-mailadres projectleader(s)/contact person | s.sleijfer@erasmusmc.nl , n.beije@erasmusmc.nl (Nick Beije, study coordinator) |
| 5. Title Project | Sensitivity to cisplatin chemotherapy determined in circulating tumor cells |
| 6. How many patients are involved in the project | We aim to enroll 10 patients in this study with ≥ 5 CTCs and a sensitive CTC Cisplatin profile. Based on the interim analysis performed here, we expect that approximately 70 patients in total will have to be enrolled to identify this number of patients. |
| 7. Description progress project, (max 350 words) | <p>July 2013 – August 2014</p> <ul style="list-style-type: none"> - Approval of CCMO, central ethics committee and local ethics committees in three different centers (Erasmus MC, Ikazia Ziekenhuis, Sint Franciscus Gasthuis) - After approval procedures, opening of three additional centers to boost patient accrual - Positive and negative control testing of CTC characterization to ensure optimal CTC characterization quality - Enrollment of 16 patients to date - Determination of the CTC cisplatin sensitivity profile in the first 14 patients enrolled in this study - Monitoring of patient eligibility and data in two centers |
| 8. Results | Two patients with ≥ 5 CTCs and a sensitive CTC cisplatin profile have been identified in the first 14 patients who were enrolled in this study. Clinical data of these patients will remain confidential until 10 patients with a sensitive CTC cisplatin profile have been enrolled. Since 2/14 patients harbor a sensitive CTC cisplatin profile and have ≥ 5 CTCs, we expect that 56 more patients have to be included to identify a total of 10 patients with ≥ 5 CTCs and a sensitive CTC cisplatin profile. Since accrual has been slower than expected in the three centers, three additional centers have been added to boost patient accrual, namely, University Hospital Antwerp (June 2014), GZA St. Augustinus Hospital Antwerp (June 2014) and Albert Schweitzer Hospital Dordrecht (August 2014). Other centers have shown interest in participating in this study as well. We expect that the required number of patients will be included within 2 years from now. |

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| <p>9. Short summary in English for the website/newsletter A Sister's Hope</p> | <p>Outcome in metastatic breast cancer patients who have already had several types of chemotherapy is in general very poor and obvious benefits are experienced only by a small group of patients. What is needed for these patients, is a way to determine beforehand which patient will benefit from which sort of chemotherapy. The Erasmus MC Cancer Institute is investigating whether the examination of circulating tumor cells (CTCs) by using a simple blood test can predict whether or not a patient will benefit from cisplatin, which is a certain kind of chemotherapy with anti-tumor activity in metastatic breast cancer.</p> <p>When a cancer cell is found in the blood stream, this is called a circulating tumor cell (CTC). This cancer cell has detached from the tumor and is able to cause distant metastases in diverse organs by moving through the blood stream. These CTCs can be counted and isolated out of the blood for molecular characterization in our laboratory.</p> <p>This is one of the first studies in the world which is investigating whether molecular characteristics found in CTCs, can be used to determine whether or not a patients will respond to a certain kind of chemotherapy. In this study, women with metastatic breast cancer, who have been treated with several kinds of chemotherapy but now show progression of disease, are all treated with cisplatin. We have recently developed a method which by giving insight into the molecular characteristics of CTCs, could possibly predict sensitivity to cisplatin. By performing this method in patients receiving cisplatin, we would possibly be able to determine which patients will benefit from cisplatin chemotherapy in the future.</p> <p>When a positive result is achieved in this study, meaning that based on the determination of molecular characteristics of CTCs it can be predicted if a patient will benefit from cisplatin treatment, this would mean that only previously selected patients (sensitive for cisplatin) would be treated with cisplatin in the future. Furthermore, treatment with cisplatin would be withheld in patients of who we know who will not respond to cisplatin chemotherapy in the future. This study fits perfectly in our philosophy of moving towards more personalized cancer care. The financial support by A Sister's Hope enables us to perform this promising research. In the coming years, we hope that through these kind of collaborations we can achieve a significant improvement in the treatment of women with metastatic breast cancer.</p> | | | | | | | | | | | | | | | |
| <p>10. Assigned subsidy</p> | <p>€ 60.000</p> | | | | | | | | | | | | | | | |
| <p>11. Received subsidy</p> | <p>€ 60.000</p> | | | | | | | | | | | | | | | |
| <p>12. Comprehensive detailed financial accountability/specification expenses (such as: personnel incl. fte's, travel, room and board, courses and conference costs, materials, other costs)</p> | <p><u>Labware/consumables</u></p> <table border="0"> <tr> <td>CTC enumeration</td> <td>275 euro/test</td> <td>€ 4400</td> </tr> <tr> <td>CTC isolation</td> <td>110 euro/test</td> <td>€ 1760</td> </tr> <tr> <td>Nucleic acid isolation from CTCs</td> <td>60 euro/test</td> <td>€ 960</td> </tr> <tr> <td>CTC characterization by q-RT PCR</td> <td>300 euro/test</td> <td>€ 4800</td> </tr> <tr> <td>CTC characterization positive and negative controls</td> <td>470 euro/test</td> <td>€ 5640</td> </tr> </table> <p><u>Other</u></p> | CTC enumeration | 275 euro/test | € 4400 | CTC isolation | 110 euro/test | € 1760 | Nucleic acid isolation from CTCs | 60 euro/test | € 960 | CTC characterization by q-RT PCR | 300 euro/test | € 4800 | CTC characterization positive and negative controls | 470 euro/test | € 5640 |
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| | Shipping costs samples 30 euro/shipping € 480 | | | | | | | | | | | | | | | | | | |
| | Total € 18.040 | | | | | | | | | | | | | | | | | | |
| 13. Detailed preview next year (incl. expected results and costs) | <ul style="list-style-type: none"> - Accrual of patients will continue (~35 expected, August 2014-August 2015) - Determination of CTC cisplatin sensitivity profiles for all patients (August 2014 – August 2015) <p><u>Budget August 2014 – August 2015:</u> <u>Labware/consumables</u></p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">CTC enumeration</td> <td style="width: 20%;">275 euro/test</td> <td style="width: 20%; text-align: right;">€ 10175</td> </tr> <tr> <td>CTC isolation</td> <td>110 euro/test</td> <td style="text-align: right;">€ 4070</td> </tr> <tr> <td>Nucleic acid isolation from CTCs</td> <td>60 euro/test</td> <td style="text-align: right;">€ 2220</td> </tr> <tr> <td>CTC characterization by q-RT PCR</td> <td>300 euro/test</td> <td style="text-align: right;">€ 11100</td> </tr> </table> <p><u>Other</u></p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">Shipping costs samples</td> <td style="width: 20%;">30 euro/shipping</td> <td style="width: 20%; text-align: right;">€ 1110</td> </tr> <tr> <td>Total</td> <td></td> <td style="text-align: right;">€ 28.675</td> </tr> </table> | CTC enumeration | 275 euro/test | € 10175 | CTC isolation | 110 euro/test | € 4070 | Nucleic acid isolation from CTCs | 60 euro/test | € 2220 | CTC characterization by q-RT PCR | 300 euro/test | € 11100 | Shipping costs samples | 30 euro/shipping | € 1110 | Total | | € 28.675 |
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| 14. Follow-up incl. PR opportunities A Sister's Hope | Not applicable yet | | | | | | | | | | | | | | | | | | |
| 15. Publications, please add realized articles/publications, summary workshops and so forth. | <p>Dr. Anieta Sieuwerts is an invited speaker at the International Advances in Circulating Tumor Cells (ACTC) symposium, where she will present some preliminary results regarding our CTC characterization assay.</p> <p>Further publications and articles are expected after completion of this study (2015-2016).</p> | | | | | | | | | | | | | | | | | | |
| 16. How will continuation of financing be arranged after A Sister's Hope? | Not applicable yet | | | | | | | | | | | | | | | | | | |
| 17. Remarks | <p>As mentioned above, the patient accrual is slower than expected. This is translated into the amount of expenses so far. Because the primary objective of this study – can molecular characteristics of CTCs be used to identify patient likely to benefit from a certain kind of chemotherapy - appears to be very appealing to other investigators as well, we have been able to increase the number of participating centers. Thereby, this A Sister's Hope supported study is now ongoing in 6 hospitals ensuring that the primary objective will be answered.</p> | | | | | | | | | | | | | | | | | | |