結論

本治験には日本人 44 名（CT 20 名、CTB5 12 名、CTB+ 12 名）が登録された。登録された全 44 名を ESP、43 名を FAS（CT 19 名、CTB5 12 名、CTB+ 12 名）とし、それぞれ安全性評価及び有効性評価を実施した。

有効性評価では、CTB5 及び CTB+の無増悪生存期間及び生存期間の中央値が得られなかったため、治療群間の比較はできなかった。

安全性評価では、ベバシズマブ（15mg/kg）が投与された CTB5 及び CTB+の有害事象発現率及び内容に CT と比較して特記すべき違いはみられなかった。よって、新しい治療法としての「ベバシズマブの化学療法との同時併用治療」及び「ベバシズマブの化学療法との同時併用治療＋維持療法」の安全性については、従来の標準的化学療法と比べて劣るものではなく認容可能と考えられた。また、FACT-O TOI の平均スコアの推移から、ベバシズマブが投与された CTB5 及び CTB+では調査期間を通して QOL の改善傾向が

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