8. BÖLÜM

GÜNÜMÜZDE YENİ İLAÇ MOLEKÜLÜ KEŞFİNDE TOKSİKOLOJİ ÇALIŞMALARI

Özge CEMİLOĞLU ÜLKER[1]

1. İLACIN TANIMI VE ÖNEMİ

İlaç / beşeri ilaç terimi şu biçimde tanımlanmıştır: "Hastalığı önlemek, teşhis etmek ve/veya tedavi etmek, fizyolojik bir fonksiyonu düzeltmek, düzenlemek veya değiştirmek amacıyla insana uygulanan doğal veya sentetik kaynaklı aktif madde maddeler kombinasyonu." (Resmî Gazete, 2008)

Yeni ilaç geliştirme, çok pahalı ve uzun bir süreçtir. Yaklaşık 12-15 yıl süren araştırmalar sonucunda ancak yeni ilaç molekülü piyasaya sürülebilmektedir. İlaç geliştirme çalışmalarında, 2013 yılı verilerine göre ruhsat sonrası Ar-Ge çalışmaları da dahil edildiğinde 2.87 milyar $'ı bulan maliyetler söz konusudur (Dimasi, Grabowski *ve ark*., 2016). Ayrıca bu süreçte gelişen tek ufak hata tüm verilerin değerini kaybetmesine neden olabilmektedir. Bunun için preklinik ve klinik çalışmaların, iyi bir ekip ile, kaliteli ekipmanlar ve ideal şartlarda düzgün olarak yürütülmesi çok önemlidir. Bunların içerisinde, klinik araştırmalara geçmeden önce yapılması gereken ve büyük öneme sahip çalışmalardan biri de toksikoloji testleridir. Şekil 1'de gösterildiği gibi yeni ilaç molekülü için patent başvurusundan sonra klinik araştırmalara kadar geçen sürede toksisite testleri uygulanmalıdır. Günümüzde toksisite testlerinin amacı, toplumsal ihtiyaçlar için yeni ilaç moleküllerinin piyasaya sürülmeden önce güvenli olup olmadıkları ile ilgili bir değerlendirme yapabilmeye olanak sağlayan verileri elde etmek ve elde edilen bu verilerden veri tabanı geliştirmektir.

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tüphanelerin eksik olması, bazı sonuç noktaların basit modellenmesi, modellerin zayıf alan uygulanabilirliği ve düzenleyici kurumlar tarafından onaylanmaması şeklinde sıralanabilir (Cronin, 2002; Ambuja, Elaina *ve ark.*,2013; Kleandrova, Luan *ve ark.,* 2015).

Bütün bu dezavantajlarına rağmen, yeni yaklaşım metadolojileri, gelişen biyoloji ve bilgisayar bilimine paralel olarak sürekli gelişmektedir. İlaç araştırmalarında da valide edilmiş, kılavuzları ve protokolleri yayınlanmış toksisite testlerinin İyi Laboratuvar Uygulamaları da dikkate alınarak yapılması, sonuçlarının değerlendirilmesi, Klinik Faz çalışmalarına geçişte ve sonrasında piyasaya sürülmesinde büyük önem taşımaktadır.

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